See Reverse for OMB Statement

FORM APPROVED: OMB No. 0910-0469. Expiration Date: July 31, 2007

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. REGI	USTRATION NUMBER Establishment (dentifier):		a.∏ IN∏	FOR SUBMISSION FIAL REGISTRATION / LISTING NUAL REGISTRATION / LISTING	VALIDATION - FOR FDA USE ONLY	
ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/P) (See reverse side for instructions)	MENT REGISTRATION AND LISTING FOR HUMAN CELLS, FISSUES, FEI: 0001570984 C. CHANGE (See reverse side for instructions) CHANGE C. INACTIVE							
PART I - ESTABLISHMENT INFORMATION	PART II - PROD	DUCT INF	FORMATION					
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMEN				na - 🗔			
a. BLOOD FOA 2830 NO. FEI: 0001570984	a X RECO		_	e X PROCES	SS g X	LABEL	VALIDATED BY FDA: 12-DEC-2005	
b. DEVICES FDA 2891 NO.	b X SCRE	EN	d X PACKAGE	1 X STORE	ħ X	DISTRIBUTE	PRINTED BY FOA: 12-DEC-2005 DISTRICT OFFICE: Cincinnati	
c. DRUG FDA 2656 NO.		1	11.		CT/Ps	13.	•	
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Community Blood Center dba Community Tissue Services	TYPES OF HCT/Ps		HCT/Ps DESCRIBED IN 21 CFR 1271.10	AS I DEVICES	MEDICAL S, DRUGS, OR IICAL DRUGS		(OPRIETARY NAME(S)	
349 S. Main Street Dayton, Ohio 45402	a	Bane	x		-			
	b, Car	rtdage	х					
PHONE 937-461-3450 EXT 3288	c. C	Comea	-			·		
		Mater						
5. ENTER CORRECTIONS TO ITEM 4		embnyo				<u></u>		
		Fascia	Х					
·	g. Heart	Valve	X					
 MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) 	h, Ligs	sament	X					
Community Blood Center/Community Tissue Services	į, O	Docyte						
349 S. Main Street Dayton, Ohio 45402	j. Perica	ardium	x	 				
PHONE 937-461-3450 EXT 3288	k, Peripheral Stem	Blood Cells	х		x			
	l. S	Sciera.						
7. ENTER CORRECTIONS TO ITEM 6	m S	Semen:						
	n.	Skin	X					
	o. Somatic	Cells						
8. U.S. AGENT	<u> </u>	eriokan	Х					
	q. Umbilical Blood Stem	n Cells						
a. E-MAIL b. PHONE	r Vascular	Grafi	X					
9. REPORTING OFFICIAL'S SIGNATURE	s.							
	L .							
a. TYPEO NAME Judith E. Woll, MD	U.							
b. E-MAIL jwoll@cbccts.org	v.							
c. TITLE CEO d. DATE 29-NOV-2005	γ.	- 1						

FORM APPROVED: OMB No. 0910-0469. Expiration Date: July 31, 2007

DEF	PARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. REGISTRATION NUMBER (Field Establishment Identifier):		FOR SUBMISSION IAL REGISTRATION / LISTING	VALIDATIONFOR FDA USE ONLY 1
	EGISTRATION AND LISTING FOR HUMAN CELLS		FEI: 0001570984	c. CHA	IUAL REGISTRATION / LISTING INGE IN INFORMATION	
DARTI FOTARIJOUMENT	(See reverse side for instructions)	DADT# 0000		d. NAC	CTIVE	*0001570984*
PART I - ESTABLISHMENT 3. OTHER FDA REGISTRATIONS		10. ESTABLISHMEN	OUCT INFORMATION			0001370964
a. BLOOD FDA 2830	NO. FEI: 0001570984	a X RECO		e X PROCESS g X	LABEL	
a. BLOOD FDA 2830 b. DEVICES FDA 2891	NO.	b X SCREE			DISTRIBUTE	VALIDATED BY FDA: 12-JAN-2007 PRINTED BY FDA: 02-FEB-2007
B. DEVICES FDA 2091	NO					DISTRICT OFFICE: Cincinnati
c. DRUG FDA 2656	NO		11.	12. HCT/Ps	13.	
post office code)	e legal name, number and street, city, state, country, and r dba Community Tissue Services	TYPES OF HCT/Ps	HCT/Ps DESCRIBED IN 21 CFR 1271.10	REGULATED AS MEDICAL DEVICES, DRUGS, OR BIOLOGICAL DRUGS	PR	OPRIETARY NAME(S)
349 S. Main Street Dayton, Ohio 45402		a.	Bone X			
•		b. Car	tilage X			
PHONE 937-461-3450	EXT 3288	c. Co	ornea			
		d. Dura I	Mater			
5. ENTER CORRECTIONS TO ITE	EM 4	e. Er	mbryo			
		f, F	ascia X			
		g. Heart	Valve X			
6. MAILING ADDRESS OF REPO number and street, city, state, cou	RTING OFFICIAL (Include institution name if applicable, untry, and post office code)	h. Liga	ament X			
Community Blood Center Attn: Judith E. Woll, MD	dba Community Tissue Services	i. O	locyte			
349 S. Main Street Dayton, Ohio 45402-271	5	j. Perical	rdium X			
		k. Peripheral E		X		
PHONE 937-461-3261	EXT	I. S	Sclera			
7. ENTER CORRECTIONS TO ITE		m. S	emen			
		n.	Skin X			
		o. Somatic	Cells			
8. U.S. AGENT		p. Te	endon X			
		q. Umbilical Blood Stem				
a. E-MAIL	b. PHONE	r. Vascular	Graft X			
9. REPORTING OFFICIAL'S SIGN	NATURE	S.				
		t.				
a. TYPED NAME Judith E. Wo	oll, MD					
b. E-MAIL jwoll@cbccts.org	•	u.				
c. TITLE CEO	d. DATE 01-DEC-2006	v.				

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)

1. REGISTRATION NUMBER (Field Establishment Identifier)
FEI: 0001570984

2. REASON FOR SUBMISSION a. INITIAL REGISTRATION / LISTING b. ANNUAL REGISTRATION / LISTING c. X CHANGE IN INFORMATION

VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:04-JAN-2008 DISTRICT: Cincinnati PRINTED BY FDA:04-FEB-2008

(See reverse side for instructions)	>)					d.	INAC	TIVE						
PART I - ESTABLISHMENT INFORMATION	PART II - P	PART II - PRODUCT INFORMATION										ME R 12	B B B 3	
3. OTHER FDA REGISTRATIONS	10. ESTABLIS	HMENT FUNCTION	NS AND	TYPES	OF HC	T / Ps					SCR SCR 12	DIC.	Series	
a. BLOOD FDA 2830 NO. FEI: 0001570984					Es	tablishr	nent Fu	nctions			71.10	ATEI Sd.	SICA PER P	14. PROPRIETARY NAME(S)
b. DEVICES FDA 2891 NO.	Types	of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10) AS EVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	in E(o)
c. DRUG FDA 2656 NO	No HCT / P S	specified											. ,	
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and	a. Bone	•	X	X	X	X	X	X	X	X	X			
post office code) Community Blood Center dba Community Tissue Services" 349 S. Main Street	b. Cartilage		X	X	X	X	X	X	X	X	X			
Dayton, Ohio 45402	c. Cornea													
	d. Dura Mater													
a. PHONE 937-461-3450 EXT 3610 b. SATELLITE RECOVERY ESTABLISHMENT	e. Embryo	SIP Directed Anonymous												
c. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia		X	X	X	X	X	X	X	X	X			
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve		X	X							X			
	h. Ligament		X	X	X	X	X	X	X	X	X			
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte	SIP Directed Anonymous												
Community Blood Center dba Community Tissue Services" Attn: David M. Smith, MD	j. Pericardium		X	X							X			
349 S. Main Street Dayton, Ohio 45402-2715	k. Peripheral Blood Stem Cells	X Autologous ☐ Family Related X Allogeneic	X	X	X	X	X	X	X	X	X		X	
	I. Sclera													
a. PHONE 937-461-3450 EXT 3610	m. Semen	SIP Directed Anonymous												
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin		X	X	X	X	X	X	X	X	X			
	o. Somatic Cells	Autologous Family Related Allogeneic												
8. U.S. AGENT	p. Tendon		X	X	X	X	X	X	X	X	X			
	q. Umbilical Cord Blood Stem Cells	☐ Autologous ☐ Family Related ☐ Allogeneic												
a. E-MAIL	r. Vascular Graft		X	X							X			
9. REPORTING OFFICIAL'S SIGNATURE	S.													
a. TYPED NAME David M. Smith, MD	t.													
b. E-MAIL dsmith@cbccts.org	u.													
c. TITLE CEO/Medical Director d. DATE 03-JAN-2008	v.													

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)

1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 0001570984

a. INITIAL REGISTRATION / LISTING b. X ANNUAL REGISTRATION / LISTING c. CHANGE IN INFORMATION

2. REASON FOR SUBMISSION

*^^^1=7^^0

(See reverse side for instructions)	>)					d.	INAC	TIVE			DIS	TRICT: C	incinnati	10/07 PRINTED By FDA: 12/17/07
PART I - ESTABLISHMENT INFORMATION	PART II - P	RODUCT INFOR	RMATIC	N							유민.	음교 12 음교 12	B R R 13.	
3. OTHER FDA REGISTRATIONS	10. ESTABLIS	HMENT FUNCTION	NS AND	TYPES							SCR 127	음문국	S GIF	
a. BLOOD FDA 2830 NO. <u>FEI: 0001570984</u>					Es	tablishn	nent Fu	nctions			Ps 1.10			14. PROPRIETARY NAME(S)
b. DEVICES FDA 2891 NO	Types	of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute	IN 21) AS EVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	`,
c. DRUG FDA 2656 NO.	No HCT / P S	pecified					<u> </u>	<u> </u>						
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)	a. Bone	•	X	X	X	X	X	X	X	X	X			
Community Blood Center dba Community Tissue Services" 349 S. Main Street Dayton, Ohio 45402	b. Cartilage		X	X	X	X	X	X	X	X	X			
Dayton, Onto 45402	c. Cornea													
	d. Dura Mater													
a. PHONE 937-461-3450 EXT 3610 b. SATELLITE RECOVERY ESTABLISHMENT	e. Embryo	SIP Directed Anonymous												
c. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia		X	X	X	X	X	X	X	X	X			
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve		X	X							X			
	h. Ligament		X	X	X	X	X	X	X	X	X			
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte	SIP Directed Anonymous												
Community Blood Center dba Community Tissue Services" Attn: David M. Smith, MD	j. Pericardium		X	X							X			
349 S. Main Street Dayton, Ohio 45402-2715	k. Peripheral Blood Stem Cells	X Autologous Family Related Allogeneic	X	X	X	X	X	X	X	X	X		X	
	I. Sclera													
a. PHONE 937-461-3450 EXT 3610	m. Semen	SIP Directed Anonymous												
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin		X	X	X	X	X	X	X	X	X			
	o. Somatic Cells	Autologous Family Related Allogeneic												
8. U.S. AGENT	p. Tendon		X	X	X	X	X	X	X	X	X			
	q. Umbilical Cord Blood Stem Cells	Autologous Family Related Allogeneic												
a. E-MAIL	r. Vascular Graft		X	X							X			
9. REPORTING OFFICIAL'S SIGNATURE	S.													
a. TYPED NAME David M. Smith, MD	t.													
b. E-MAIL dsmith@cbccts.org	u.													
c. TITLE CEO/Medical Director d. DATE 05-DEC-2007	٧.													

FORM APPROVED: OMB No. 0910-0543. Expiration Date: 7/31/10 See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)

1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 0001570984

2. REASON FOR SUBMISSION a. | INITIAL REGISTRATION / LISTING b. ANNUAL REGISTRATION / LISTING c. X CHANGE IN INFORMATION

VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:27-MAR-2008 DISTRICT: Cincinnati PRINTED BY FDA:27-MAR-2008

(See reverse side for instructions)						d. [INAC	TIVE						
PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION									11. CH	돌교 12.	B R R 13		
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps										HCT SCRI R 12	읈	Sent	
a. BLOOD FDA 2830 NO. FEI: 0001570984					Est	tablishn	nent Fui	nctions			/Ps BED 71.10	E E S	SICA REIS	14. PROPRIETARY NAME(S)
b. DEVICES FDA 2891 NO.	Types of HCT	·/Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute	IN 21	D AS EVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	(0)
c. DRUG FDA 2656 NO	No HCT / P Specifie	ed											, , , , , , , , , , , , , , , , , , ,	
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)	a. Bone		X	X	X	X	X	X	X	X	X			
Community Blood Center dba Community Tissue Services 349 S. Main Street	b. Cartilage		X	X	X	X	X	X	X	X	X			
Dayton, Ohio 45402	c. Cornea													
	d. Dura Mater													
a. PHONE 937-461-3450 EXT 3610 b. SATELLITE RECOVERY ESTABLISHMENT	e. Embryo	SIP Directed Anonymous												
c. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia		X	X	X	X	X	X	X	X	X			
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve		X	X							X			
	h. Ligament		X	X	X	X	X	X	X	X	X			
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)		SIP Directed Anonymous												
Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD	j. Pericardium		X	X	X	X	X	X	X	X	X			
349 S. Main Street Dayton, Ohio 45402-2715	Blood Stem F	Autologous Family Related Allogeneic	X	X	X	X	X	X	X	X	X		X	
	I. Sclera													
a. PHONE 937-461-3450 EXT 3610 7. ENTER CORRECTIONS TO ITEM 6	m. Semen Semen	SIP Directed Anonymous												
b. PHONE	n. Skin		X	X	X	X	X	X	X	X	X			
	0. Somatic F	Autologous Family Related Allogeneic												
8. U.S. AGENT	p. Tendon		X	X	X	X	X	X	X	X	X			
	Cord Blood F	Autologous Family Related Allogeneic												
a. E-MAIL	r. Vascular Graft		X	X							X			
9. REPORTING OFFICIAL'S SIGNATURE	s.													
a. TYPED NAME David M. Smith, MD	t.													
b. E-MAIL dsmith@cbccts.org	u.													
c. TITLE CEO/Medical Director d. DATE 20-MAR-2008	V.													

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)

1. REGISTRATION NUMBER (Field Establishment Identifier)

FEI: 0001570984

2. REASON FOR SUBMISSION a. INITIAL REGISTRATION / LISTING | VALIDATED BY FDA:30-DEC-2008 b. X ANNUAL REGISTRATION / LISTING CHANGE IN INFORMATION

VALIDATION--FOR FDA USE ONLY DISTRICT: Cincinnati PRINTED BY FDA:05-JAN-2009

(See reverse side for instructions)					d	INAC	TIVE						
PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFOR	RMATIC	ON							11. CF	돌유 12.	B R R 13.	
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTION	NS AND	TYPES	OF HC	T / Ps					HCT SCRI R 12	등등학	S S S S	
a. BLOOD FDA 2830 NO. FEI: 0001570984			1	Es	tablishn	nent Fu	nctions			11. HCT/Ps DESCRIBED I CFR 1271.10	L A A	SICA ATE	14. PROPRIETARY NAME(S)
b. DEVICES FDA 2891 NO.	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute	IN 21	OAS	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	Will (O)
c. DRUG FDA 2656 NO												86	
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)	a. Bone	X	X	X	X	X	X	X	X	X			
Community Blood Center dba Community Tissue Services 349 S. Main Street	b. Cartilage	X	X	X	X	X	X	X	X	X			
Dayton, Ohio 45402	c. Cornea												
	d. Dura Mater												
a. PHONE 937-461-3450 EXT 3610 b. SATELLITE RECOVERY ESTABLISHMENT	e. Embryo SIP Directed Anonymous												
b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO c. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia	X	X	X	X	X	X	X	X	X			
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve	X	X							X			
	h. Ligament	X	X	X	X	X	X	X	X	X			
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte SIP Directed Anonymous												
Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD	j. Pericardium	X	X	X	X	X	X	X	X	X			
349 S. Main Street Dayton, Ohio 45402-2715	k. Peripheral Blood Stem Cells Autologous Family Related Allogeneic	X	X	X	X	X	X	X	X	X			
	I. Sclera												
a. PHONE 937-461-3450 EXT 3610	m. Semen SIP Directed Anonymous												
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin	X	X	X	X	X	X	X	X	X			
	o. Somatic Cell Autologous Therapy Family Related Products Allogeneic												
8. U.S. AGENT	p. Tendon	X	X	X	X	X	X	X	X	X			
	q. Umbilical Autologous Cord Blood Family Related Stem Cells Allogeneic												
a. E-MAIL	r. Vascular Graft	X	X							X			
9. REPORTING OFFICIAL'S SIGNATURE	s. Parathyroid					X	X		X	X			
a. TYPED NAME David M. Smith, MD	t. Peritoneal Membrane	X	X	X	X	X	X	X	X	X	<u> </u>		
b. E-MAIL dsmith@cbccts.org	u.												
c. TITLE CEO/Medical Director d. DATE 08-DEC-2008	V.												

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS. TISSUES.

1. REGISTRATION NUMBER (Field Establishment Identifier)

a. INITIAL REGISTRATION / LISTING VALIDATED BY FDA:08-JUL-2009 b. ANNUAL REGISTRATION / LISTING DISTRICT: Cincinnati

2. REASON FOR SUBMISSION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps (See reverse side for instructions)		c. X CHANGE IN INFORMATION									PF	PRINTED BY FDA:10-AUG-2009				
PART I - ESTABLISHMENT INFORMATION	PART II - PRO	DDUCT INFOR	ΜΔΤΙΟ	N		u	IIVAO	1111			13. HCT/Ps REGULATED AS BIOLOGICAL DRUGS OR REGULATED AS					
3. OTHER FDA REGISTRATIONS	10. ESTABLISHM				OF HC	T / Ps					# SS 등	E G K	P E E E			
a. BLOOD FDA 2830 NO. FEI: 0001570984		Establishment Functions										A A A	SSA	14. PROPRIETARY		
b. DEVICES FDA 2891 NO.	Types of F	HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute	0 IN 21	D AS	D AS	NAME(S)		
c. DRUG FDA 2656 NO													Ö			
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)	a. Bone		X	X	X	X	X	X	X	X	X					
Community Blood Center dba Community Tissue Services 349 S. Main Street	b. Cartilage		X	X	X	X	X	X	X	X	X					
Dayton, Ohio 45402	c. Cornea				X						X					
	d. Dura Mater															
a. PHONE 937-461-3450 EXT 3610 b. SATELLITE RECOVERY ESTABLISHMENT		SIP Directed Anonymous														
c. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia		X	X	X	X	X	X	X	X	X					
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve		X	X	X						X					
	h. Ligament		X	X	X	X	X	X	X	X	X					
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte	SIP Directed Anonymous														
Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD	j. Pericardium		X	X	X	X	X	X	X	X	X					
349 S. Main Street Dayton, Ohio 45402-2715	Blood Stem	X Autologous Family Related Allogeneic	X	X	X	X	X	X	X	X	X					
	I. Sclera				X						X					
a. PHONE 937-461-3450 EXT 3610		SIP Directed Anonymous														
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin		X	X	X	X	X	X	X	X	X					
	Therapy	X Autologous Family Related Allogeneic	X			X							X			
8. U.S. AGENT	p. Tendon		X	X	X	X	X	X	X	X	X					
	Cord Blood	Autologous Family Related Allogeneic														
a. E-MAIL	r. Vascular Graft		X	X	X						X					
9. REPORTING OFFICIAL'S SIGNATURE	s. Parathyroid						X	X		X	X					
a. TYPED NAME David M. Smith, MD	t. Peritoneal Memb	orane	X	X	X	X	X	X	X	X	X					
b. E-MAIL dsmith@cbccts.org	u.															
c. TITLE CEO d. DATE 29-JUN-2009	V.															

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)

1. REGISTRATION NUMBER (Field Establishment Identifier)

FEI: 0001570984

2. REASON FOR SUBMISSION a. INITIAL REGISTRATION / LISTING b. X ANNUAL REGISTRATION / LISTING c. CHANGE IN INFORMATION

VALIDATED BY FDA:05-JAN-2010 DISTRICT: Cincinnati PRINTED BY FDA:23-FEB-2010

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(See reverse side for instructions)				d. NACTIVE										
PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION										DES CFR	돌유12	무무요3	
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps									R SCR	음문	D S E E		
a. BLOOD FDA 2830 NO. FEI: 0001570984					Est	ablishm	ent Fur	nctions			71.1C	A PER S	S S A S	14. PROPRIETARY NAME(S)
b. DEVICES FDA 2891 NO.	Types of HC	Types of HCT / Ps		Screen	Test	Package	Process	Store	Label	Distribute	. HCT/Ps ESCRIBED IN 21 R 1271.10	D AS EVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	NAIVIE(3)
c. DRUG FDA 2656 NO												-	S	
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)	a. Bone		X	X	X	X	X	X	X	X	X			
Community Blood Center dba Community Tissue Services 349 S. Main Street	b. Cartilage		X	X	X	X	X	X	X	X	X			
Dayton, Ohio 45402	c. Cornea				X						X			
	d. Dura Mater													
a. PHONE 937-461-3450 EXT 3610 b. SATELLITE RECOVERY ESTABLISHMENT] SIP] Directed] Anonymous												
c. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia		X	X	X	X	X	X	X	X	X			
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve		X	X	X						X			
	h. Ligament		X	X	X	X	X	X	X	X	X			
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte	SIP Directed Anonymous												
Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD	j. Pericardium		X	X	X	X	X	X	X	X	X			
349 S. Main Street Dayton, Ohio 45402-2715	Blood Stem	Autologous Family Related Allogeneic	X	X	X	X	X	X	X	X	X			
	I. Sclera				X						X			
a. PHONE 937-461-3450 EXT 3610	m. Semen] SIP] Directed] Anonymous												
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin		X	X	X	X	X	X	X	X	X			
	Therapy	Autologous Family Related Allogeneic	X			X							X	
8. U.S. AGENT	p. Tendon		X	X	X	X	X	X	X	X	X			
	Cord Blood	Autologous Family Related Allogeneic												
a. E-MAIL	r. Vascular Graft		X	X	X						X			
9. REPORTING OFFICIAL'S SIGNATURE	s. Parathyroid						X	X		X	X			
a. TYPED NAME David M. Smith, MD	t. Peritoneal Membra	ane	X	X	X	X	X	X	X	X	X			
b. E-MAIL dsmith@cbccts.org	u.													
c. TITLE CEO d. DATE 29-DEC-2009	v.													

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)

1. REGISTRATION NUMBER
(Field Establishment Identifier)

FEI: 0001570984

2. REA	SON FOR SUBMISSION
a. 🗌	INITIAL REGISTRATION / LISTING
b. X	ANNUAL REGISTRATION / LISTIN
c. 🗌	CHANGE IN INFORMATION

VALIDATION--FOR FDA USE ONLY G VALIDATED BY FDA:29-DEC-2010 NG DISTRICT: Cincinnati PRINTED BY FDA:05-JAN-2011

(See reverse side for instructions)	•					d.	INAC	TIVE						
PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION										11. HCT/Ps DESCRIBED I CFR 1271.10	음교 2	B 등 등 13.	
3. OTHER FDA REGISTRATIONS	10. ESTABLISHM	MENT FUNCTION	IS AND	TYPES	OF HC	T / Ps					R SCR	문문되	오양하고	
a. BLOOD FDA 2830 NO. FEI: 0001570984					Es	tablishn	nent Fu	nctions			71.1	L 등 품 중기	S S A S	14. PROPRIETARY NAME(S)
b. DEVICES FDA 2891 NO.	Types of HCT / Ps Recover Screen Test Package Process Store		Store	Label	Distribute	0 IN 21	D AS EVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	NAME(3)					
c. DRUG FDA 2656 NO												Ö		
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)	a. Bone		X	X	X	X	X	X	X	X	X			
Community Blood Center dba Community Tissue Services 349 S. Main Street	b. Cartilage		X	X	X	X	X	X	X	X	X			
Dayton, Ohio 45402-2715	c. Cornea				X						X			
	d. Dura Mater													
a. PHONE 937-461-3450 EXT 3610 b. SATELLITE RECOVERY ESTABLISHMENT		SIP Directed Anonymous												
b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO c. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia		X	X	X	X	X	X	X	X	X			
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve		X	X	X						X			
	h. Ligament		X	X	X	X	X	X	X	X	X			
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte	SIP Directed Anonymous												
Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD	j. Pericardium		X	X	X	X	X	X	X	X	X			
349 S. Main Street Dayton, Ohio 45402-2715	Blood Stem	X Autologous Family Related Allogeneic	X	X	X	X	X	X	X	X	X			
	I. Sclera				X						X			
a. PHONE 937-461-3450 EXT 3610	m. Semen	SIP Directed Anonymous												
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin		X	X	X	X	X	X	X	X	X			
	Therapy	X Autologous Family Related Allogeneic	X			X							X	
8. U.S. AGENT	p. Tendon		X	X	X	X	X	X	X	X	X			
	Cord Blood	Autologous Family Related Allogeneic												
a. E-MAIL	r. Vascular Graft		X	X	X						X			
9. REPORTING OFFICIAL'S SIGNATURE	s. Parathyroid						X	X		X	X			
a. TYPED NAME David M. Smith, MD	t. Peritoneal Memb	orane	X	X	X	X	X	X	X	X	X			
b. E-MAIL dsmith@cbccts.org	u.													
	v.									+		\vdash		
c. TITLE CEO d. DATE 21-DEC-2010	\ \frac{\sqrt{1}}{1}											, !		

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,

(Field Establishment Identifier) FEI: 0001570984

1. REGISTRATION NUMBER

2. REASON FOR SUBMISSION a. INITIAL REGISTRATION / LISTING | VALIDATED BY FDA:08-DEC-2011 b. X ANNUAL REGISTRATION / LISTING CHANGE IN INFORMATION

VALIDATION--FOR FDA USE ONLY DISTRICT: Cincinnati PRINTED BY FDA:15-DEC-2011

AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)

(See reverse side for instructions)						d.	INAC ⁻	TIVE						
PART I - ESTABLISHMENT INFORMATION	PART II - PRODUC	T INFORMA	ATIOI	N					DES CFR	MR 12.	무무요3			
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT F	UNCTIONS A	AND T	YPES	OF HC	Γ/Ps			SCR SCR 12	음	오양타리			
a. BLOOD FDA 2830 NO. FEI: 0001570984					Est	ablishm	ent Fu	nctions]	. HCT/Ps SCRIBED I R 1271.10	FE A	S S A S	14. PROPRIETARY NAME(S)
b. DEVICES FDA 2891 NO.	Types of HCT / Ps		cover	Screen	Test	Package	Process	Store	Label	Distribute	N 21	D AS EVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	NAME(O)
c. DRUG FDA 2656 NO													š	
 PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) 	a. Bone	-	X	X	X		X	X	X	X	X			
Community Blood Center dba Community Tissue Services 349 S. Main Street	b. Cartilage	,	X	X	X		X	X	X	X	X			
Dayton, Ohio 45402-2715	c. Cornea				X						X			
	d. Dura Mater													
a. PHONE 937-461-3450 EXT 3610 b. SATELLITE RECOVERY ESTABLISHMENT	e. Embryo SIP Direc	cted nymous												
c. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia		X	X	X		X	X	X	X	X			
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve		X	X	X						X			
	h. Ligament		X	X	X		X	X	X	X	X			
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte SIP Direc													
Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD	j. Pericardium	-	X	X	X		X	X	X	X	X			
349 S. Main Street Dayton, Ohio 45402-2715	k. Peripheral X Autol Blood Stem Fami Cells Allogo	ly Related	X	X	X	X	X	X	X	X	X			
	I. Sclera				X						X			
a. PHONE 937-461-3450 EXT 3610 7. ENTER CORRECTIONS TO ITEM 6	m. Semen SIP Direct	cted nymous												
b. PHONE	n. Skin	-	X	X	X		X	X	X	X	X			
	o. Somatic Cell X Autol Therapy Fami Products Allog	ly Related	X			X							X	
8. U.S. AGENT	p. Tendon		X	X	X		X	X	X	X	X			
	q. Umbilical Autol Cord Blood Fami Stem Cells Allog	ly Related												
a. E-MAIL	r. Vascular Graft		X	X	X						X			
9. REPORTING OFFICIAL'S SIGNATURE	s. Parathyroid						X	X		X	X			
a. TYPED NAME David M. Smith, MD	t. Peritoneal Membrane		X	X	X		X	X	X	X	X			
b. E-MAIL dsmith@cbccts.org	u.													
c. TITLE CEO d. DATE 07-DEC-2011	v.													

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)

(FDA Establishment Identifier) FEI: 0001570984

1. REGISTRATION NUMBER

a. INITIAL REGISTRATION / LISTING b. X ANNUAL REGISTRATION / LISTING c. CHANGE IN INFORMATION

2. REASON FOR SUBMISSION

VALIDATED BY FDA:21-NOV-2012 DISTRICT: Cincinnati PRINTED BY FDA:06-DEC-2012

(See reverse side for instructions)						d.	INAC	TIVE						
PART I - ESTABLISHMENT INFORMATION	PART II - P	RODUCT INFOR	RMATIC	N					유민.1	MR 12.	무무교3			
3. OTHER FDA REGISTRATIONS	10. ESTABLISH	HMENT FUNCTION	NS AND	TYPES	OF HC	T / Ps			R 12	음음	S S S S S S S S S S S S S S S S S S S			
a. BLOOD FDA 2830 NO. FEI: 0001570984					Est	ablishm	ent Fu	nctions			11. HCT/Ps DESCRIBED I CFR 1271.10	E E E	S S A F S	14. PROPRIETARY NAME(S)
b. DEVICES FDA 2891 NO.	Types o	Types of HCT / Ps		Recover Screen Test P		Package	Process	Store	Label	Distribute	N 21	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	(O)
c. DRUG FDA 2656 NO													SS	
 PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) 	a. Bone		X	X	X		X	X	X	X	X			
Community Blood Center dba Community Tissue Services	b. Cartilage		X	X	X		X	X	X	X	X			
349 S. Main Street Dayton, Ohio 45402-2715	c. Cornea			X	X						X			
	d. Dura Mater													
a. PHONE 937-461-3450 EXT 3610	e. Embryo	SIP Directed Anonymous												
b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. C: TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia		X	X	X		X	X	X	X	X			
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve		X	X	X						X			
	h. Ligament		X	X	X		X	X	X	X	X			
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte	SIP Directed Anonymous												
Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD	j. Pericardium		X	X	X		X	X	X	X	X			
349 S. Main Street Dayton, Ohio 45402-2715	k. Peripheral Blood Stem	Autologous Family Related Allogeneic	X	X	X	X	X	X	X	X	X			
	I. Sclera				X						X			
a. PHONE 937-461-3450 EXT 3610	m. Semen	SIP Directed Anonymous												
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin		X	X	X		X	X	X	X	X			
	o. Somatic Cell Therapy Products	Autologous Family Related Allogeneic	X			X							X	
8. U.S. AGENT	p. Tendon		X	X	X		X	X	X	X	X			
	q. Umbilical Cord Blood	Autologous Family Related Allogeneic												
a. E-MAIL	r. Vascular Graft		X	X	X						X			
9. REPORTING OFFICIAL'S SIGNATURE	s. Parathyroid						X	X		X	X			
a. TYPED NAME David M. Smith, MD	t. Peritoneal Me	mbrane	X	X	X		X	X	X	X	X			
•	u.													
b. E-MAIL dsmith@cbccts.org														
c. TITLE CEO d. DATE 20-NOV-2012	V.													

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)

1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 0001570984

a. INITIAL REGISTRATION / LISTING b. X ANNUAL REGISTRATION / LISTING

VALIDATED BY FDA:19-NOV-2013 DISTRICT: Cincinnati PRINTED BY FDA:09-DEC-2013

VALIDATION--FOR FDA USE ONLY

c. CHANGE IN INFORMATION

2. REASON FOR SUBMISSION

AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps (See reverse side for instructions)	CTS (HCT/Ps) c. CHANGE IN INFORMATION d. INACTIVE													
PART I - ESTABLISHMENT INFORMATION	PART II - P	RODUCT INFOR	RMATIC	N							유료:	MR 12.	B R R 13.	
OTHER FDA REGISTRATIONS	10. ESTABLISI	HMENT FUNCTION	NS AND	TYPES	OF HC	T / Ps					11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	SET	D C C C C C C C C C C C C C C C C C C C	
a. BLOOD FDA 2830 NO. FEI: 0001570984					Es	tablishn	nent Fun	octions			/Ps BED 71.10	L PEE	SCA SEE	14. PROPRIETARY NAME(S)
b. DEVICES FDA 2891 NO	Types o	Types of HCT / Ps Recover Screen		Test	Package	Process	Store	Label	Distribute	IN 21	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	.,	
c. DRUG FDA 2656 NO													o l	
. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and cost office code)	a. Bone		X	X	X			X	X	X	X			
Community Blood Center dba Community Tissue Services	b. Cartilage		X	X	X			X	X	X	X			
349 S. Main Street Dayton, Ohio 45402-2715	c. Cornea			X	X						X			
Dayton, Onto 45402-2713	d. Dura Mater													
a. PHONE 937-461-3450 EXT 3610	e. Embryo	SIP Directed Anonymous												
b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO.	f. Fascia		X	X	X			X	X	X	X			
c. TESTING FOR MICRO-ORGANISMS ONLY ENTER CORRECTIONS TO ITEM 4	g. Heart Valve		X	X	X						X			
	h. Ligament		X	X	X			X	X	X	X			
. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte	SIP Directed Anonymous												
Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD	j. Pericardium		X	X	X			X	X	X	X			
349 S. Main Street Dayton, Ohio 45402-2715	k. Peripheral Blood Stem	Autologous Family Related Allogeneic	X	x	X	X		X	х	X	X			
	I. Sclera			X	X						X			
a. PHONE 937-461-3450 EXT 3610	m. Semen	SIP Directed												
. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin	Anonymous	X	X	X			X	X	X	X			
	o. Somatic Cell Therapy Products	X Autologous Family Related Allogeneic	X			X							X	
. U.S. AGENT	p. Tendon		X	X	X			X	X	X	X			
	q. Umbilical Cord Blood	Autologous Family Related Allogeneic												
a. E-MAIL	r. Vascular Graft		X	X	X						X			
REPORTING OFFICIAL'S SIGNATURE	s. Parathyroid							X	X	X	X			
TYPED NAME David M. Smith, MD	t. Peritoneal Me	mbrane	X	X	X			X	X	X	X			
b. E-MAIL dsmith@cbccts.org	u.													
c. TITLE CEO d. DATE 18-NOV-2013	V.													

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 1/31/14 2 DEASON FOR SURMISSION

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION FSTARI ISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS. TISSUES.

2. REASON FOR SUBMISSION	
a. INITIAL REGISTRATION / LISTING	G
b. ANNUAL REGISTRATION / LISTIN	N
c. X CHANGE IN INFORMATION	

VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:31-DEC-2013 DISTRICT: Cincinnati

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELL: AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/P (See reverse side for instructions)		FEI: 00015	70984			1 =	X CHAN	IGE IN IN		TION	PF	RINTED	BY FDA:27	FDA:27-JAN-2014
PART I - ESTABLISHMENT INFORMATION	PART II - PR	ODUCT INFOR	RMATIC	ON.		u					유무크	돌교12	B 등 교 3	
3. OTHER FDA REGISTRATIONS	10. ESTABLISHN				OF HC	T / Ps					#SS 5	EBC H	13. HCT/Ps REGULATED / DRUGS OR BIOLOGICAL I	
a. BLOOD FDA 2830 NO. FEI: 0001570984							nent Fu	nctions			7/Ps	AT AT S	GGC,	14. PROPRIETARY
b. DEVICES FDA 2891 NO	Types of I	HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	ED AS	NAME(S)
c. DRUG FDA 2656 NO													GS	
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and	a. Bone		X	X	X		X	X	X	X	X			
post office code) Community Blood Center dba Community Tissue Services	d. Bono													
Community Fisca Community Fisca Services	b. Cartilage		X	X	X		X	X	X	X	X			
349 S. Main Street Dayton, Ohio 45402-2715	c. Cornea			X	X						X			
	d. Dura Mater													
a. PHONE 937-461-3450 EXT 3610	e. Embryo	SIP Directed Anonymous												
b. ☐ SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO C. ☐ TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia		X	X	X		X	X	X	X	X			
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve		X	X	X						X			
	h. Ligament		X	X	X		X	X	X	X	X			
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte	SIP Directed Anonymous												
Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD	j. Pericardium		X	X	X		X	X	X	X	X			
349 S. Main Street Dayton, Ohio 45402-2715	Blood Stem	X Autologous Family Related Allogeneic	X	X	X	X	X	X	X	X	X			
	I. Sclera			X	X						X			
a. PHONE 937-461-3450 EXT 3610 7. ENTER CORRECTIONS TO ITEM 6	m. Semen	SIP Directed Anonymous												
b. PHONE	n. Skin		X	X	X		X	X	X	X	X			
	o. Somatic Cell Therapy Products	X Autologous Family Related Allogeneic	X			X							X	
8. U.S. AGENT	p. Tendon		X	X	X		X	X	X	X	X			
	Cord Blood	Autologous Family Related Allogeneic												
a. E-MAIL	r. Vascular Graft		X	X	X		X				X			
9. REPORTING OFFICIAL'S SIGNATURE	s. Parathyroid						X	X	X	X	X			
a. TYPED NAME David M. Smith, MD	t. Peritoneal Memb	orane	X	X	X		X	X	X	X	X			
b. E-MAIL dsmith@cbccts.org	u.													
c. TITLE CEO d. DATE 30-DEC-2013	v.													
U. DATE 30-DEC-2013	1		1	1	1	1	1	I	1	1		I		

1. REGISTRATION NUMBER

(FDA Establishment Identifier)

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)

1. REGISTRATION NUMBER
(FDA Establishment Identifier)

FEI: 0001570984

2. REASON FOR SUBMISSION a. INITIAL REGISTRATION / LISTING b. X ANNUAL REGISTRATION / LISTING c. CHANGE IN INFORMATION

VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:02-DEC-2014 DISTRICT: Cincinnati PRINTED BY FDA:22-DEC-2014

PART IL - PRODUCT INFORMATION S. STABLESHMENT INFORMATION S.	(See reverse side for instructions)	5)					d. [TIVE						
### A PRISEAL LOCATION (Policials legis) arrange, number and street, city, status, country, and post office acids) ### A PRISEAL LOCATION (Policials legis) arrange and street, city, status, country, and post office acids) ### A PRISEAL LOCATION (Policials legis) arrange and street, city, status, country, and post office acids ### A PRISEAL LOCATION TO TITEM ### A PRISEAL LOCA	PART I - ESTABLISHMENT INFORMATION	PART II - PI	RODUCT INFOR	RMATIC	N				유명.1	MR 12.	B R R 13.				
a. RPRIGH TOA. 2668 NO. A. PRISEAL LOCATION (relius tegral paraer, number and street, chy, stone, country, and post office oxios) A. RESTREE CONTINUED (Plotted by Community Tissue Services 349 S. Main Street Disviou, Ohio 43402-2715 a. PHONE 937-461-3450 b. Castilage x. x	3. OTHER FDA REGISTRATIONS	10. ESTABLISH	IMENT FUNCTION	S AND	TYPES	OF HC	T / Ps			RSCT 12	E HOE	Section			
### A PRISEAL LOCATION (Policials legis) arrange, number and street, city, status, country, and post office acids) ### A PRISEAL LOCATION (Policials legis) arrange and street, city, status, country, and post office acids) ### A PRISEAL LOCATION (Policials legis) arrange and street, city, status, country, and post office acids ### A PRISEAL LOCATION TO TITEM ### A PRISEAL LOCA	a. BLOOD FDA 2830 NO. FEI: 0001570984				1	Es	tablishn	nent Fu	nctions		,	/Ps	E SES	SCA SE'S	14. PROPRIETARY NAME(S)
### A PRISEAL LOCATION (Policials legis) arrange, number and street, city, status, country, and post office acids) ### A PRISEAL LOCATION (Policials legis) arrange and street, city, status, country, and post office acids) ### A PRISEAL LOCATION (Policials legis) arrange and street, city, status, country, and post office acids ### A PRISEAL LOCATION TO TITEM ### A PRISEAL LOCA	b. DEVICES FDA 2891 NO.	Types of	Types of HCT / Ps		Screen	Test	Package	Process	Store	Label	Distribute	N 21	D AS EVICES	D AS L DRUG	(- /
Description codes Description Descript														S	
349 S. Main Street Dayton, Ohio 45402-2715 C. Comes X X X X X X X X X X X X X X X	post office code)	a. Bone		X	X	X		X	X	X	X	X			
Dayton, Ohio 45402-2715	Community Blood Center dba Community Tissue Services	b. Cartilage		X	X	X		X	X	X	X	X			
S. PHONE 937-461-3450 EXT 3610 Signature Recovery establishment Fin No. Signature Recovery establishmen		c. Cornea			X	X						X			
a. PHONE 937-461-3450 EXT 3610 a. PHONE 937-461-3450 EXT 3610 b. □ SAFELITE RECOVERY ESTABLISHMETER c. □ TESTING FOR MICKO-ORGANISMS ONLY 5. ENTER CORRECTIONS TO ITEM 4 6. MALING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Community Blood Center dha Community Tissue Services After: David M. Smith, MD 349 S. Main Street Dayson, Ohio 45402-2715 a. PHONE 937-461-3450 EXT 3610 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE a. E. MALING STATE ALL (Include institution name if applicable, number and street, city, state, country, and post office code) I. Occyte I. Docyte I. Docyte I. Docyte II. Docyte II. Docyte III. III. III. III. III. III. III. II		d. Dura Mater													
Community Comm	a. PHONE 937-461-3450 EXT 3610	e. Embryo	☐ Directed												
S. ENTER CORRECTIONS TO ITEM 4	(MANUFACTURING ESTABLISHMENT FEI NO	f. Fascia		X	X	X		X	X	X	X	X			
Community Blood Center dba Community Tissue Services Dayton, Ohio 45402-2715 SIP Dayton, Ohio 45402-2715 Extra Corrections to ITEM 6 D. PHONE		g. Heart Valve		X	X	X						X			
Anonymous Anon		h. Ligament		X	X	X		X	X	X	X	X			
Attr: David M. Smith, MD 349 S. Main Street Dayton, Ohio 45402-2715 R. Peripheral Dayton, Ohio 45402-2715 R. Peripheral Dayton, Ohio 45402-2715 R. Peripheral Dayton, Ohio 45402-2715 R. Selera		i. Oocyte													
Section Sect		j. Pericardium		X	X	X		X	X	X	X	X			
SIP Directed Anonymous Directed Anonymous Directed Directed Anonymous Directed	349 S. Main Street		Family Related	X	X	X	X	X	X	X	X	X			
Annymous		I. Sclera			X	X						X			
Definition Def		m. Semen	SIP Directed Aponymous												
Therapy	7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin		X	X	X		X	X	X	X	X			
a. E-MAIL 9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME David M. Smith, MD b. E-MAIL dsmith@cbccts.org		Therapy		X	X	X	X	X						X	
Cord Blood	8. U.S. AGENT	p. Tendon		X	X	X		X	X	X	X	X			
S. Parathyroid X X X X X X X X X X X X X X X X X X			☐ Family Related												
a. TYPED NAME David M. Smith, MD b. E-MAIL dsmith@cbccts.org		r. Vascular Graft		X	X	X		X				X			
a. TYPED NAME David M. Smith, MD b. E-MAIL dsmith@cbccts.org	9. REPORTING OFFICIAL'S SIGNATURE	s. Parathyroid						X	X	X	X	X			
b. E-MAIL dsmith@cbccts.org	a. TYPED NAME David M. Smith. MD		nbrane	X	X	X		X	X	X	X	X			
		u.													
		v.													

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,

1. REGISTRATION NUMBER	2. REASON FOR SUBMISSION
(FDA Establishment Identifier)	a. INITIAL REGISTRATION / LISTING
FEI: 0001570984	b. ANNUAL REGISTRATION / LISTIN
121. 0001370984	c. X CHANGE IN INFORMATION

VALIDATION--FOR FDA USE ONLY
VALIDATED BY FDA:14-APR-2015 NG DISTRICT: Cincinnati
PRINTED BY FDA:22-JUN-2015

AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps (See reverse side for instructions))	d. [FURIVIA	ION				
PART I - ESTABLISHMENT INFORMATION	PART II - P	RODUCT INFOR	RMATIC	ON							2B.3	돌유1 ₂	B 2 2 3	
3. OTHER FDA REGISTRATIONS		HMENT FUNCTION			OF HC	T / Ps					R CR	SEE	다. 이 없는 다.	
a. BLOOD FDA 2830 NO. FEI: 0001570984					Es	tablishr	nent Fu	nctions			71.10	PATE	SICA SICA SICA SICA SICA SICA SICA SICA	14. PROPRIETARY NAME(S)
b. DEVICES FDA 2891 NO.	Types o	of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	(0)
c. DRUG FDA 2656 NO													S	
 PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) 	a. Bone		X	X	X		X	X	X	X	X			
Community Blood Center dba Community Tissue Services	b. Cartilage		X	X	X		X	X	X	X	X			
349 S. Main Street Dayton, Ohio 45402-2715	c. Cornea			X	X						X			
	d. Dura Mater													
a. PHONE 937-461-3450 EXT 3610	e. Embryo	SIP Directed Anonymous												
b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. C. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia		X	X	X		X	X	X	X	X			
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve		X	X	X						X			
	h. Ligament		X	X	X		X	X	X	X	X			
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte	SIP Directed Anonymous												
Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD	j. Pericardium		X	X	X		X	X	X	X	X			
349 S. Main Street Dayton, Ohio 45402-2715	k. Peripheral Blood Stem	X Autologous Family Related Allogeneic	X	X	X	X	X	X	X	X	X			
	I. Sclera			X	X						X			
a. PHONE 937-461-3450 EXT 3610	m. Semen	SIP Directed Anonymous												
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin		X	X	X		X	X	X	X	X			
	o. Somatic Cell Therapy Products	X Autologous Family Related X Allogeneic	x	X	X	X	x						X	
8. U.S. AGENT	p. Tendon		X	X	X		X	X	X	X	X			
	q. Umbilical Cord Blood	☐ Autologous ☐ Family Related ☐ Allogeneic												
a. E-MAIL	r. Vascular Graft		X	X	X		X				X			
9. REPORTING OFFICIAL'S SIGNATURE	s. Parathyroid							X	X	X	X			
a. TYPED NAME David M. Smith, MD	t. Peritoneal Me	mbrane	X	X	X		X	X	X	X	X			
b. E-MAIL dsmith@cbccts.org	u.													
c. TITLE CEO d. DATE 13-APR-2015	V.													

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

FEI: 0001570984

1. REGISTRATION NUMBER

(FDA Establishment Identifier)

a. INITIAL REGISTRATION / LISTING b. x ANNUAL REGISTRATION / LISTING

2. REASON FOR SUBMISSION

VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:17-NOV-2015 DISTRICT: Cincinnati PRINTED BY FDA:03-DEC-2015

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,
AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)

d. DATE 16-NOV-2015

CHANGE IN INFORMATION (See reverse side for instructions) d. NACTIVE 12. HCT/Ps REGULATED AS MEDICAL DEVICES PART I - ESTABLISHMENT INFORMATION **PART II - PRODUCT INFORMATION** 3. OTHER FDA REGISTRATIONS 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps 14. PROPRIETARY **Establishment Functions** NO. FEI: 0001570984 a. BLOOD FDA 2830 NAME(S) N 21 Types of HCT / Ps Recover Screen Package Process Label Distribute b. DEVICES FDA 2891 NO. c. DRUG FDA 2656 4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and X \mathbf{X} X X X \mathbf{X} X a. Bone post office code) Community Blood Center dba Community Tissue Services X \mathbf{X} X X X X X b. Cartilage 349 S. Main Street \mathbf{X} X c. Cornea Dayton, Ohio 45402-2715 d. Dura Mater e. Embryo Directed a. PHONE 937-461-3450 EXT 3610 Anonymous b. SATELLITE RECOVERY ESTABLISHMENT \mathbf{X} \mathbf{X} \mathbf{X} \mathbf{X} \mathbf{X} X \mathbf{X} f. Fascia (MANUFACTURING ESTABLISHMENT FEI NO. TESTING FOR MICRO-ORGANISMS ONLY X X X g. Heart Valve 5. ENTER CORRECTIONS TO ITEM 4 X X X X X X \mathbf{X} h. Ligament ☐ SIP Directed Oocyte 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, ☐ Anonymous number and street, city, state, country, and post office code) Community Blood Center dba Community Tissue Services \mathbf{X} j. Pericardium X X X X X X Attn: David M. Smith, MD x Autologous k. Peripheral 349 S. Main Street Family Related \mathbf{X} X \mathbf{X} X X X X X Blood Stem Dayton, Ohio 45402-2715 Allogéneic X \mathbf{X} I. Sclera SIP Directed m. Semen a. PHONE 937-461-3450 EXT 3610 Anonymous 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE X X X X X X X n. Skin o. Somatic Cell X Autologous Therapy Family Related X X \mathbf{X} X X Products x Allogeneic 8. U.S. AGENT X \mathbf{X} X \mathbf{X} X \mathbf{X} X p. Tendon q. Umbilical Autologous Family Related Cord Blood Allogeneic X \mathbf{X} X X r. Vascular Graft a. E-MAIL 9. REPORTING OFFICIAL'S SIGNATURE s. Parathyroid X X X \mathbf{X} t. Peritoneal Membrane \mathbf{X} X X X X X X a. TYPED NAME David M. Smith, MD b. E-MAIL dsmith@cbccts.org

c. TITLE CEO

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)

1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 0001570984

a. INITIAL REGISTRATION / LISTING b. X ANNUAL REGISTRATION / LISTING c. CHANGE IN INFORMATION

2. REASON FOR SUBMISSION

VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:07-DEC-2016 DISTRICT: Cincinnati PRINTED BY FDA:15-DEC-2016

(See reverse side for instructions)						d.	INAC	TIVE						
PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION									유명.4	≦R.12.	BR 13.		
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT	FUNCTIONS	SAND	TYPES	OF HC	T / Ps					R SS T	음음	S G C C C C C C C C C C C C C C C C C C	
a. BLOOD FDA 2830 NO. FEI: 0001570984					Est	ablishn	nent Fu	nctions			71.1(Ps	무료공 무료공	SCAE'S	14. PROPRIETARY NAME(S)
b. DEVICES FDA 2891 NO.	Types of HCT / Ps		Recover	Screen	Test	Package	Process	Store	Label	Distribute	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	Train L(O)
c. DRUG FDA 2656 NO													š	
 PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) 	a. Bone		X	X			X	X	X	X	X			
Community Blood Center dba Community Tissue Services	b. Cartilage		X	X			X	X	X	X	X			
349 S. Main Street Dayton, Ohio 45402-2715	c. Cornea			X							X			
	d. Dura Mater													
a. PHONE 937-461-3450 EXT 3610	e. Embryo SIP	ected onymous												
b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. C. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia		X	X			X	X	X	X	X			
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve		X	X							X			
	h. Ligament		X	X			X	X	X	X	X			
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte SIF	ected onymous												
Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD	j. Pericardium		X	X			X	X	X	X	X			
349 S. Main Street Dayton, Ohio 45402-2715	k. Peripheral X Auto Blood Stem Fam Allo	ologous nily Related geneic	X	X		X	X	X	X	X	X			
	I. Sclera			X							X			
a. PHONE 937-461-3450 EXT 3610	m. Semen SIP	ected onymous												
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin		X	X			X	X	X	X	X			
		ologous nily Related geneic	X	X		X	X						X	
8. U.S. AGENT	p. Tendon		X	X			X	X	X	X	X			
	q. Umbilical Auto	ologous nily Related ogeneic												
a. E-MAIL	r. Vascular Graft		X	X			X				X			
9. REPORTING OFFICIAL'S SIGNATURE	s. Parathyroid							X	X	X	X			
a. TYPED NAME David M. Smith, MD	t. Peritoneal Membrane		X	X			X	X	X	X	X			
· ·	u.													
b. E-MAIL dsmith@cbccts.org							-							
c. TITLE CEO d. DATE 06-DEC-2016	V.													