See Reverse for OWA Statement FORM APPROVED: OMB No. 0910-0469. Expiration Date: July 31, 2007

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

PART I - ESTABLISHMENT INFORMATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)

1 REGISTRATION NUMBER (Field Establishment Identifier): EEF 3000718784

2. REASON FOR SUBMISSION a. [1] INITIAL REGISTRATION/LISTING

b. X ANNUAL REGISTRATION / LISTING CHANGE IN INFORMATION

d. ☐ INACTIVE

VALIDATION-FOR FDAUSE ONLY

10. ESTABLISHMENT FUNCTIONS: g X LABEL PROCESS a X RECOVER c TEST h X DISTRIBUTE 1 X STORE d PACKAGE b X SCREEN

PART II - PRODUCT INFORMATION

3. OTHER FOA REGISTRATIONS VALIDATED BY FDA: 12-DEC-2005 a. BLOOD FDA 2830 PRINTED BY FOA: 12-DEC-2005 OISTRICT OFFICE: Cincinnati b. DEVICES FDA 2891 11. 12. c. DRUG FDA 2656 **HCT/Ps** REGULATED HCT/Ps PROPRIETARY NAME(S) AS MEDICAL 4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and TYPES OF DESCRIBED IN DEVICES, DRUGS, OR HCT/Ps ලයෝ අසිය හැරව 21 CFR 1271.10 BIOLOGICAL DRUGS Community Blood Center dba Community Tissue Services Bone а X 2736 N. Holland-Sylvania Road Toledo, Ohio 43615 Cartilage b. X PHONE 419-536-4924 EXT Comea Œ. X Dura Mater ď. Embryo 5. ENTER CORRECTIONS TO ITEM 4 Fascia f. X Heart Valve βL X 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, Ligament h, X number and street, city, state, country, and post office code) Community Blood Center/Community Tissue Services Occule 349 South Main Street Pericentium Dayton, Ohio 45402-2715 X Peripheral Blood k. EXT 3288 PHONE 937-461-3450 Stem Calls Sclera 1. Х 7. ENTER CORRECTIONS TO ITEM 6 Semen Щ, Slán n. Х Somatic Calls a. 8. U.S. AGENT Tendon X p, Umbilical Cord Blood Stem Cells Vascular Graft r, Х b. PHONE a. E-MAIL S. 9. REPORTING OFFICIAL'S SIGNATURE ŧ. a. TYPED NAME Judith E. Woll, MD u.

d. DATE 29-NOV-2005

a.TITLE CEO

b. E-MAIL jwoll@cbccts.org

FORM APPROVED: OMB No. 0910-0469. Expiration Date: July 31, 2007 2. REASON FOR SUBMISSION VALIDATION--FOR FDA USE ONLY 1. REGISTRATION NUMBER DEPARTMENT OF HEALTH AND HUMAN SERVICES a. NITIAL REGISTRATION / LISTING (Field Establishment Identifier): FOOD AND DRUG ADMINISTRATION b. X ANNUAL REGISTRATION / LISTING ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, FEI: 3000718784 c. CHANGE IN INFORMATION AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions) INACTIVE *3000718784* **PART I - ESTABLISHMENT INFORMATION PART II - PRODUCT INFORMATION** 3. OTHER FDA REGISTRATIONS 10. ESTABLISHMENT FUNCTIONS: a X RECOVER c TEST e PROCESS g X LABEL a. BLOOD FDA 2830 VALIDATED BY FDA: 12-JAN-2007 d PACKAGE b X SCREEN f X STORE h X DISTRIBUTE PRINTED BY FDA: 02-FEB-2007 b. DEVICES FDA 2891 NO. DISTRICT OFFICE: Cincinnati 13. c. DRUG FDA 2656 11. HCT/Ps REGULATED HCT/Ps 4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and PROPRIETARY NAME(S) TYPES OF AS MEDICAL DESCRIBED IN post office code) HCT/Ps DEVICES, DRUGS, OR 21 CFR 1271.10 **BIOLOGICAL DRUGS** Community Blood Center dba Community Tissue Services Bone 2736 N. Holland-Sylvania Road a. \mathbf{X} Toledo, Ohio 43615 Cartilage b. X PHONE 419-536-4924 EXT Cornea C. \mathbf{X} Dura Mater d. 5. ENTER CORRECTIONS TO ITEM 4 Embryo e. Fascia f. \mathbf{X} Heart Valve g. X 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, Ligament h. X number and street, city, state, country, and post office code) Community Blood Center dba Community Tissue Services Oocyte Attn: Judith E. Woll, MD 349 South Main Street Pericardium \mathbf{X} Dayton, Ohio 45402-2715 Peripheral Blood k. Stem Cells Sclera 1. X PHONE 937-461-3261 EXT 7. ENTER CORRECTIONS TO ITEM 6 m. Skin n. X Somatic Cells 0. 8. U.S. AGENT Tendon p. X **Umbilical Cord** q. Blood Stem Cells Vascular Graft r. X a. E-MAIL b. PHONE 9. REPORTING OFFICIAL'S SIGNATURE S. t. a. TYPED NAME Judith E. Woll, MD u. b. E-MAIL jwoll@cbccts.org

٧.

d. DATE 01-DEC-2006

c. TITLE CEO

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

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	2. REASON FOR SUBMISSION
(Field Establishment Identifier)	a. INITIAL REGISTRATION / LISTING
FEI: 3000718784	b. X ANNUAL REGISTRATION / LISTING
FEI. 3000/10/04	OLIANIOE IN INFORMATION

ING c. CHANGE IN INFORMATION

2000710701

VALIDATION--FOR FDA USE ONLY

(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 - PI	PART II - PRODUCT INFORMATION										음교 12 음교 12	B R R 13.	
3. OTHER FDA REGISTRATIONS	10. ESTABLISH	IMENT FUNCTION	NS AND	TYPES							SCRI SCRI 7 127	유민	DLOG GOLL HCT	44 PROPRIETARY
a. BLOOD FDA 2830 NO		Establishment Functions											E SEE	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			
Community Blood Center dba Community Tissue Services" 2736 N. Holland-Sylvania Road	b. Cartilage		X	X				X	X	X	X			
Toledo, Ohio 43615	c. Cornea		X	X							X			
	d. Dura Mater													
a. PHONE 419-536-4924 EXT b. SATELLITE RECOVERY ESTABLISHMENT	e. Embryo	SIP Directed Anonymous												
c. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia		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			
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 South Main Street Dayton, Ohio 45402-2715	k. Peripheral Blood Stem Cells	Autologous Family Related Allogeneic												
	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			
	o. Somatic Cells	Autologous Family Related Allogeneic												
8. U.S. AGENT	p. Tendon		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	v.													

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: 3000718784

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													
PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION							PART II - PRODUCT INFORMATION									다. 유민	음교 12	13. RE DR BIG	
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMEN	ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps							SCR 12	「음등관」	Sent Ger HCJ									
a. BLOOD FDA 2830 NO					Est	tablishm	nent Fur	nctions			/Ps	E # 3	SICA SIE	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	D AS EVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	NAME(3)						
c. DRUG FDA 2656 NO.	No HCT / P Specifie	nd.								L										
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and	1	,u	X	X				**	X 7	X	X									
post office code) Community Blood Center dba Community Tissue Services	a. Bone		Λ	Λ				X	X	A	Α	<u> </u>								
2736 N. Holland-Sylvania Road	b. Cartilage		X	X				X	X	X	X									
Toledo, Ohio 43615	c. Cornea		X	X							X									
	d. Dura Mater																			
a. PHONE 419-536-4924 EXT 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									
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve		X	X							X									
	h. Ligament		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									
349 South Main Street Dayton, Ohio 45402-2715	Blood Stem F	Autologous Family Related Allogeneic																		
	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									
	o. Somatic F	Autologous Family Related Allogeneic																		
8. U.S. AGENT	p. Tendon		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.																			
TYPED NAME David M. Carida M.D.	t.											l ⁷								
a. TYPED NAME David M. Smith, MD	u.																			
b. E-MAIL dsmith@cbccts.org						-						$\vdash \vdash$								
c. TITLE CEO/Medical Director d. DATE 20-MAR-2008	V.											i '								

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 8/31/10

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

2. REASON FOR SUBMISSION
a. INITIAL REGISTRATION / LISTING
VALIDATION--FOR FDA US
VALIDATION--FOR FDA US VALIDATION--FOR FDA USE ONLY

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)	FEI: 3000718784	b. X ANNUAL REGISTRATION / LISTING c. CHANGE IN INFORMATION d. INACTIVE	PRINTED BY FDA:05-JAN-2009
--	-----------------	---	----------------------------

1. REGISTRATION NUMBER (Field Establishment Identifier)

(Gee reverse side for instructions)					u. [INAC	IIVE							
PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFOR	RMATIC	ON							11. HCT/Ps DESCRIBED I CFR 1271.10	MR 12.	13. HCT/Ps REGULATED / DRUGS OR BIOLOGICAL I		
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTION	ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps						12 SCR	음등	Sent Gent HCJ				
a. BLOOD FDA 2830 NO				Es	tablishr	nent Fui	nctions			/Ps	ATE /P	SCA SE	14. PROPRIETARY NAME(S)	
b. DEVICES FDA 2891 NO.	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute	z	12. HCT/Ps REGULATED AS MEDICAL DEVICES	D AS L DRUGS	NAME(O)	
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				
Community Blood Center dba Community Tissue Services 2736 N. Holland-Sylvania Road	b. Cartilage	X	X				X	X	X	X				
Toledo, Ohio 43615	c. Cornea	X	X							X				
	d. Dura Mater													
a. PHONE 419-536-4924 EXT b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO	e. Embryo SIP Directed Anonymous													
c. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia	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				
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				
349 South Main Street Dayton, Ohio 45402-2715	k. Peripheral Autologous Blood Stem Family Related Cells Allogeneic													
	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				
	o. Somatic Cell Autologous Therapy Family Related Products Allogeneic													
8. U.S. AGENT	p. Tendon	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				
a. TYPED NAME David M. Smith, MD	t. Peritoneal Membrane	X	X				X	X	X	X				
b. E-MAIL dsmith@cbccts.org	u.													
c. TITLE CEO/Medical Director d. DATE 08-DEC-2008	v.													
d. DATE ON-DEC-2008														

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 8/31/10

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: 3000718784

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

VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:05-JAN-2010 DISTRICT: Cincinnati PRINTED BY FDA:23-FEB-2010

(See reverse side for instructions)					d	INAC	TIVE						
PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFO	T INFORMATION									AR 12.	명무교3	
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTION	0. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps							HCT/ HCT/ HCT/ HCT/ HCT/ HCT/ HCT/ HCT/			<u> </u>	
a. BLOOD FDA 2830 NO.				Es	tablishn	nent Fui	nctions			/Ps	ATE /PS	S S 전 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	TOATILE (O)
c. DRUG FDA 2656 NO												S	
 PHYSICAL LOCATION (Include legal name, number and street, city, state, country, post office code) 	and a. Bone	X	X				X		X	X			
Community Blood Center dba Community Tissue Services 2736 N. Holland-Sylvania Road	b. Cartilage	X	X				X		X	X			
Toledo, Ohio 43615	c. Cornea	X	X							X			
	d. Dura Mater												
a. PHONE 419-536-4924 EXT b. SATELLITE RECOVERY ESTABLISHMENT	e. Embryo SIP Directed Anonymous												
c. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia	X	X				X		X	X			
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve	X	X							X			
	h. Ligament	X	X				X		X	X			
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicanumber 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			
349 South Main Street Dayton, Ohio 45402-2715	k. Peripheral Autologous Blood Stem Family Related Cells Allogeneic												
	I. Sclera	X	X							X			
a. PHONE 937-461-3450 EXT 3610 7. ENTER CORRECTIONS TO ITEM 6	m. Semen SIP Directed Anonymous												
7. ENTER CORRECTIONS TO TIEM 6 b. PHONE	n. Skin	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			
	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. Peritoneal Membrane	X	X				X		X	X			
a. TYPED NAME David M. Smith, MD	t.												
b. E-MAIL dsmith@cbccts.org	u.												
c. TITLE CEO d. DATE 29-DEC-2	000 v.	+											
o. THEE CEO U. DATE 29-DEC-2		1		1	1	1	1	l	1	l	1		

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 8/31/10

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: 3000718784

2. REAS	SON FOR SUBMISSION
	INITIAL REGISTRATION / LISTING
b. X	ANNUAL REGISTRATION / LISTING
с. 🗌	CHANGE IN INFORMATION

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

(See reverse side for instructions)				d. [] INAC													
PART I - ESTABLISHMENT INFORMATION	RT I - ESTABLISHMENT INFORMATION PART II - PRODUCT INFORM							RMATION										
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTION	PART II - PRODUCT INFORMATION ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps Figure Figu							SET	D GS HCI								
a. BLOOD FDA 2830 NO				Es	tablishn	nent Fu	nctions			71.10 11.10		SE SEE P	14. PROPRIETARY NAME(S)					
b. DEVICES FDA 2891 NO.	Types of HCT / Ps		Screen	Test	Package	Process	Store	Label	Distribute	₹ 21	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	(0)					
c. DRUG FDA 2656 NO												Ö						
 PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) 	a. Bone	X	X				X		X	X								
Community Blood Center dba Community Tissue Services 2736 N. Holland-Sylvania Road	b. Cartilage	X	X				X		X	X								
Toledo, Ohio 43615	c. Cornea	X	X							X								
	d. Dura Mater																	
a. PHONE 419-536-4924 EXT b. SATELLITE RECOVERY ESTABLISHMENT MANUFACTURING ESTABLISHMENT FEI NO.	e. Embryo SIP Directed Anonymous																	
c. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia	X	X				X		X	X								
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve	X	X							X								
	h. Ligament	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								
349 South Main Street Dayton, Ohio 45402-2715	k. Peripheral Autologous Blood Stem Family Related Cells Allogeneic	i																
	I. Sclera																	
a. PHONE 937-461-3450 EXT 3610 7. ENTER CORRECTIONS TO ITEM 6 BRIONE	m. Semen SIP Directed Anonymous																	
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin	X	X				X		X	X								
	o. Somatic Cell Autologous Therapy Family Relater Products Allogeneic	d																
8. U.S. AGENT	p. Tendon	X	X				X		X	X								
	q. Umbilical Autologous Cord Blood Family Related Stem Cells Allogeneic	i																
a. E-MAIL	r. Vascular Graft	X	X							X								
9. REPORTING OFFICIAL'S SIGNATURE	s. Peritoneal Membrane	X	X				X		X	X								
a. TYPED NAME David M. Smith, MD	t.																	
b. E-MAIL dsmith@cbccts.org	u.																	
c. TITLE CEO d. DATE 21-DEC-2010	V.																	

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

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)

REGISTRATION NUMBER (Field Establishment Identifier)	2. REASON FOR SUBMISSION a. NITIAL REGISTRATION / LIST
FEI: 3000718784	b. X ANNUAL REGISTRATION / LIS
FEI: 3000/18/84	c. CHANGE IN INFORMATION

VALIDATION--FOR FDA USE ONLY TING VALIDATED BY FDA:08-DEC-2011 ISTING DISTRICT: Cincinnati PRINTED BY FDA:15-DEC-2011

(See reverse side for instructions)	,				d. [INAC	ΓIVE						
PART I - ESTABLISHMENT INFORMATION	PART II - PROD	PART II - PRODUCT INFORMATION									MR 12.	무무유.3	
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMEN	NT FUNCTIONS AN	D TYPES							R 12	12. HCT/Ps REGULATED AS MEDICAL DEVICES 11. HCT/Ps DESCRIBED IN 21 CFR 1371 10	P S S S S S S S S S S S S S S S S S S S	
a. BLOOD FDA 2830 NO.				Es	tablishn	nent Fur	nctions			/Ps BED 71.10	L ATE	SE SES	14. PROPRIETARY NAME(S)
b. DEVICES FDA 2891 NO.	Types of HCT	T/Ps Recove	Screen	Test	Package	Process	Store	Label	Distribute	z) AS EVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	117.1112(0)
c. DRUG FDA 2656 NO.												ισ Π	
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, post office code)	country, and a. Bone	X	X				X		X	X			
Community Blood Center dba Community Tissue Services 2736 N. Holland-Sylvania Road	b. Cartilage	X	X				X		X	X			
Toledo, Ohio 43615	c. Cornea	X	X							X			
	d. Dura Mater												
a. PHONE 419-536-4924 EXT b. SATELLITE RECOVERY ESTABLISHMENT	e. Embryo	SIP Directed Anonymous											
c. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia	X	X				X		X	X			
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve	X	X							X			
	h. Ligament	X	X				X		X	X			
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name number and street, city, state, country, and post office code)	if applicable, i. Oocyte	SIP Directed Anonymous											
Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD	j. Pericardium	X	X				X		X	X			
349 South Main Street Dayton, Ohio 45402-2715	Blood Stem	Autologous Family Related Allogeneic											
	I. Sclera												
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			
	Therapy F	Autologous Family Related Allogeneic											
8. U.S. AGENT	p. Tendon	X	X				X		X	X			
	Cord Blood	Autologous Family Related Allogeneic											
a. E-MAIL	r. Vascular Graft	X	X							X			
9. REPORTING OFFICIAL'S SIGNATURE	s. Peritoneal Membran	ne X	X				X		X	X			
a TYPED NAME David M Carid MD	t.												
a. TYPED NAME David M. Smith, MD b. E-MAIL dsmith@cbccts.org	u.												
c. TITLE CEO d. DATE 07-	DEC-2011 v.												

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

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: 3000718784

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

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

VALIDATION--FOR FDA USE ONLY

(See reverse side for instructions)					d.	INAC'	TIVE								
PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION											BR 13.			
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTION	NS AND	R SC T	HCT BE T	다. 										
a. BLOOD FDA 2830 NO.				Est	ablishn	nent Fu	nctions			11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	무료공 무료공	SCAE'S	14. PROPRIETARY NAME(S)		
b. DEVICES FDA 2891 NO.	Types of HCT / Ps		Types of HCT / Ps Recov	Recover	Screen	Test	Package	Process	Store	Label	Distribute	0 IN 21	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	NAME(O)
c. DRUG FDA 2656 NO												š			
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)	a. Bone	X	X			X	X		X	X					
Community Blood Center dba Community Tissue Services	b. Cartilage	X	X			X	X		X	X					
2736 N. Holland-Sylvania Road Toledo, Ohio 43615	c. Cornea	X	X							X					
	d. Dura Mater														
a. PHONE 419-536-4924 EXT	e. Embryo SIP Directed Anonymous														
b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO.	f. Fascia	X	X			X	X		X	X					
c. L_ TESTING FOR MICRO-ORGANISMS ONLY 5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve	X	X							X					
	h. Ligament	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					
349 South Main Street Dayton, Ohio 45402-2715	k. Peripheral Autologous Blood Stem Family Related Allogeneic	ı													
	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					
	o. Somatic Cell	ı													
8. U.S. AGENT	p. Tendon	X	X			X	X		X	X					
	q. Umbilical Autologous Cord Blood Family Related Allogeneic	ı													
a. E-MAIL	r. Vascular Graft	X	X							X					
9. REPORTING OFFICIAL'S SIGNATURE	s. Peritoneal Membrane	X	X			X	X		X	X					
	t.														
a. TYPED NAME David M. Smith, MD	u.														
b. E-MAIL dsmith@cbccts.org															
c. TITLE CEO d. DATE 20-NOV-2012	V.														

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

2. REASON FOR SUBMISSION VALIDATION—FOR FDA USE ONLY 1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION Tablishment registration and Listing for Human Cells, T REGISTRATION NUMBER
 (FDA Establishment Identifier)

FEI: 3000718784

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

VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:19-NOV-2013 DISTRICT: Cincinnati PRINTED BY FDA:09-DEC-2013

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

(See reverse side for instructions) d. NACTIVE 11. HCT/Ps DESCRIBED IN 21 CFR 1271.10 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** a. BLOOD FDA 2830 NAME(S) Types of HCT / Ps Recover Screen Package Process 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 \mathbf{X} X a. Bone post office code) Community Blood Center dba Community Tissue Services X X \mathbf{X} X X b. Cartilage 2736 N. Holland-Sylvania Road X X X c. Cornea Toledo, Ohio 43615 d. Dura Mater e. Embryo Directed a. PHONE 419-536-4924 Anonymous b. SATELLITE RECOVERY ESTABLISHMENT \mathbf{X} \mathbf{X} \mathbf{X} \mathbf{X} 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 \mathbf{X} \mathbf{X} h. Ligament ☐ SIP i. Oocyte Directed 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 Attn: David M. Smith. MD k. Peripheral Autologous 349 South Main Street ☐ Family Related Blood Stem Dayton, Ohio 45402-2715 Allogéneic X \mathbf{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 n. Skin o. Somatic Cell Autologous Therapy Family Related Products Allogeneic 8. U.S. AGENT X \mathbf{X} X \mathbf{X} X p. Tendon q. Umbilical Autologous Family Related Cord Blood Allogeneic \mathbf{X} X X r. Vascular Graft a. E-MAIL 9. REPORTING OFFICIAL'S SIGNATURE s. Peritoneal Membrane \mathbf{X} X X X \mathbf{X} a. TYPED NAME David M. Smith, MD u. b. E-MAIL dsmith@cbccts.org c. TITLE CEO d. DATE 18-NOV-2013

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULA AND TISSUE BASED BRODUCTS (HCT/Ps)

2. REASON FOR SUBMISSION 1. REGISTRATION NUMBER a. INITIAL REGISTRATION / LISTING (FDA Establishment Identifier) b. ANNUAL REGISTRATION / LISTING FEI: 3000718784 c. X CHANGE IN INFORMATION

VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:31-DEC-2013 DISTRICT: Cincinnati PRINTED BY FDA:27-JAN-2014

(See reverse side for instructions))				d. [INAC		ii OrtiviA	11014				
PART I - ESTABLISHMENT INFORMATION												무무유3	
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUN		R CR	BC HC	SEOF SEOF								
a. BLOOD FDA 2830 NO.	Establishment Functions									'/Ps IBED 71.10	F A P	SICA PER PER PER PER PER PER PER PER PER PER	14. PROPRIETARY NAME(S)
b. DEVICES FDA 2891 NO	Types of HCT / Ps		er 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	, ,
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			
Community Blood Center dba Community Tissue Services	b. Cartilage	X	X			X	X		X	X			
2736 N. Holland-Sylvania Road Toledo, Ohio 43615	c. Cornea	X	X							X			
	d. Dura Mater												
a. PHONE 419-536-4924 EXT	e. Embryo SIP Directed Anonym	d nous											
b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia	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			
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte SIP Directer Anonym												
Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD	j. Pericardium	X	X			X	X		X	X			
349 South Main Street Dayton, Ohio 45402-2715	k. Peripheral Autologo Blood Stem Family F Allogene	Related											
	I. Sclera	X	X							X			
a. PHONE 937-461-3450 EXT 3610	m. Semen SIP Directed Anonym	ous											
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin	X	X			X	X		X	X			
	o. Somatic Cell Autologo Therapy Family F Products Allogene	Related											
8. U.S. AGENT	p. Tendon	X	X			X	X		X	X			
	q. Umbilical Autologo Cord Blood Family F Allogene	Related											
a. E-MAIL	r. Vascular Graft	X	X			X				X			
9. REPORTING OFFICIAL'S SIGNATURE	s. Peritoneal Membrane	X	X			X	X		X	X			
a. TYPED NAME David M. Smith, MD	t.												
b. E-MAIL dsmith@cbccts.org	u.												
c. TITLE CEO d. DATE 30-DEC-2013	v.												

See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017

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 BRODUCTS (HCT/Pc)

1. REGISTRATION NUMBER (FDA Establishment Identifier)	2
FEI: 3000718784	

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:02-DEC-2014
DISTRICT: Cincinnati
PRINTED BY FDA:22-DEC-2014

(See reverse side for instructions))				d. [INAC		ii Oldiviza	1014				
PART I - ESTABLISHMENT INFORMATION												B 2 2 1 3.	
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUN		R SCS	SEE	SOF S	14. PROPRIETARY NAME(S)							
a. BLOOD FDA 2830 NO		Establishment Functions								/Ps BED 71.10	L ATE	SE SEE SE	
b. DEVICES FDA 2891 NO	Types of HCT / Ps		er 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	
c. DRUG FDA 2656 NO												<i>v</i>	
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)	a. Bone	X	X			X	X		X	X			
Community Blood Center dba Community Tissue Services	b. Cartilage	X	X			X	X		X	X			
2736 N. Holland-Sylvania Road Toledo, Ohio 43615	c. Cornea	X	X							X			
	d. Dura Mater												
a. PHONE 419-536-4924 EXT	e. Embryo SIP Directed Anonym	ous											
b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia	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			
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte SIP Directed Anonym												
Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD	j. Pericardium	X	X			X	X		X	X			
349 South Main Street Dayton, Ohio 45402-2715	k. Peripheral Autologo Blood Stem Family R Allogene	elated											
	I. Sclera	X	X							X			
a. PHONE 937-461-3450 EXT 3610	m. Semen SIP Directed Anonyme	ous											
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin	X	X			X	X		X	X			
	o. Somatic Cell Autologo Therapy Family R Products Allogene	elated											
8. U.S. AGENT	p. Tendon	X	X			X	X		X	X			
	q. Umbilical Autologo Cord Blood Family R Allogene	elated											
a. E-MAIL	r. Vascular Graft	X	X			X				X			
9. REPORTING OFFICIAL'S SIGNATURE	s. Peritoneal Membrane	X	X			X	X		X	X			
a. TYPED NAME David M. Smith, MD	t.												
b. E-MAIL dsmith@cbccts.org	u.												
c. TITLE CEO d. DATE 01-DEC-2014	V.												

See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

FSTARI ISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS. TISSUES.

FEI: 3000718784

1. REGISTRATION NUMBER

(FDA Establishment Identifier)

2. REASON FOR SUBMISSION a. INITIAL REGISTRATION / LISTING | VALIDATED BY FDA:17-NOV-2015 b. X ANNUAL REGISTRATION / LISTING DISTRICT: Cincinnati

VALIDATION--FOR FDA USE ONLY

AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps									PRINTED BY I DA.03-DEG-2013					
PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION											≦R12	B 등 등 3	
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT				OF HC	Γ/Ps					7 SCF C	등등 등등	S S S S S S S S S S S S S S S S S S S	
a. BLOOD FDA 2830 NO	Establishment Functions									11. HCT/Ps DESCRIBED I CFR 1271.10	PAS	GIC/Ps	14. PROPRIETARY NAME(S)	
b. DEVICES FDA 2891 NO.	Types of HCT / Ps		Recover	Screen	Test	Package	Process	Store	Label	Distribute	Z	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	NAME(3)
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			
Community Blood Center dba Community Tissue Services	b. Cartilage		X	X			X	X		X	X			
2736 N. Holland-Sylvania Road Toledo, Ohio 43615	c. Cornea		X	X							X			
	d. Dura Mater													
a. PHONE 419-536-4924 EXT	e. Embryo SIF													
b. ☐ SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. C. ☐ TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia		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			
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte SIF													
Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD	j. Pericardium		X	X			X	X		X	X			
349 South Main Street Dayton, Ohio 45402-2715	k. Peripheral Auto	ologous nily Related geneic												
	I. Sclera		X	X							X			
a. PHONE 937-461-3450 EXT 3610 7. ENTER CORRECTIONS TO ITEM 6	m. Semen SIP													
b. PHONE	n. Skin		X	X			X	X		X	X			
	Therapy	ologous nily Related ogeneic												
8. U.S. AGENT	p. Tendon		X	X			X	X		X	X			
	q. Umbilical Auto Cord Blood Fan	ologous nily Related ogeneic												
a. E-MAIL	r. Vascular Graft		X	X			X				X			
9. REPORTING OFFICIAL'S SIGNATURE	s. Peritoneal Membrane		X	X			X	X		X	X			
a. TYPED NAME David M. Smith, MD	t.													
b. E-MAIL dsmith@cbccts.org	u.													
c. TITLE CEO d. DATE 16-NOV-2015	v.													