

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> (See reverse side for instructions)	<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3014769200	<b>2. REASON FOR SUBMISSION</b> a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:15-OCT-2018 DISTRICT: Dallas PRINTED BY FDA:15-OCT-2018
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION															14. PROPRIETARY NAME(S)		
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps										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					
	Establishment Functions																	
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute									
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) United Tissue Resources, LLC  4300 N. Lamar Blvd. Austin, Texas 78756  a. PHONE 512-206-1266 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone	X	X				X		X	X	X							
	b. Cartilage	X	X				X		X	X								
	c. Cornea						X		X	X								
	d. Dura Mater																	
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																	
	f. Fascia	X	X				X		X	X								
	g. Heart Valve	X	X				X		X	X	X	X						
	h. Ligament	X	X				X		X	X	X							
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																	
	j. Pericardium	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) United Tissue Resources Attn: Wendy Bailey, CQA (ASQ) 4300 N. Lamar Blvd. Austin, Texas 78756  a. PHONE 512-206-1134 EXT _____ b. PHONE _____	k. Peripheral Blood Stem <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic						X		X	X								
	l. Sclera						X		X	X								
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																	
	n. Skin	X	X				X		X	X								
	o. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic	X				X	X	X	X	X				X				
	p. Tendon	X	X				X		X	X	X	X						
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																	
	r. Vascular Graft	X	X				X		X	X	X							
	s. Amniotic Membrane						X		X	X								
	t. Nerve Tissue	X	X				X		X	X								
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Wendy Bailey, CQA (ASQ) b. E-MAIL wbailey@tcms.com c. TITLE Director, Quality Assurance d. DATE 10-AUG-2018	u. Placenta	X	X				X		X	X								
	v. Amniotic Fluid						X		X	X								

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

Per email October 12, 2018 ORA issued a new FEI number 3014769200. The old FEI number was 0001671794.

**Proprietary Name(s):**

Additional HCT/Ps:	Functions:	Proprietary Name
Umbilical Cord	Recover, Screen	11.CFR1271(v)