

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> <i>(See reverse side for instructions)</i>		<b>1. REGISTRATION NUMBER</b> (Field Establishment Identifier)  FEI: 1000113913	<b>2. REASON FOR SUBMISSION</b> a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY  *1000113913* VALIDATED By FDA:12/03/07 PRINTED By FDA:12/07/07 DISTRICT: Florida										
<b>PART I - ESTABLISHMENT INFORMATION</b> 3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		<b>PART II - PRODUCT INFORMATION</b> 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	14. PROPRIETARY NAME(S)				
		<b>Establishment Functions</b>												
		Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
		No HCT / P Specified												
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> University of Miami Miller School of Medicine Tissue Bank 1600 NW 10th Ave #8061 Miami, Florida 33136  a. PHONE 305-243-6334 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY  5. ENTER CORRECTIONS TO ITEM 4  6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> H. Thomas Temple, M.D. Attn: H. Thomas Temple, M.D. 1600 NW 10th Ave #8061 Miami, Florida 33136  a. PHONE 305-243-6334 EXT _____ 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____  8. U.S. AGENT  a. E-MAIL 9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME H. Thomas Temple, M.D. b. E-MAIL cchin@med.miami.edu c. TITLE Director d. DATE 28-NOV-2007		a. Bone	X	X		X	X	X	X	X	X			
		b. Cartilage	X	X		X	X	X	X	X	X			
		c. Cornea												
		d. Dura Mater	X	X		X	X	X	X	X	X			
		e. Embryo												
				<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
		f. Fascia	X	X		X	X	X	X	X	X	X		
		g. Heart Valve	X	X								X		
		h. Ligament	X	X		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	X	X			
		k. Peripheral Blood Stem Cells												
				<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
		l. Sclera												
		m. Semen												
				<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
		n. Skin	X	X		X	X	X	X	X	X	X		
		o. Somatic Cells												
		<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
p. Tendon	X	X		X	X	X	X	X	X	X				
q. Umbilical Cord Blood Stem Cells														
		<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
r. Vascular Graft														
s. Trachea	X	X		X	X	X	X	X	X	X				
t.														
u.														
v.														