


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: 3004561638	<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	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA: 17-NOV-2016 DISTRICT: Detroit PRINTED BY FDA: 16-DEC-2016
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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) International Cryogenics, Inc.  32121 Woodward Ave Suite 205 Royal Oak, Michigan 48073  a. PHONE 248-397-8449 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone																					
	b. Cartilage																					
	c. Cornea																					
	d. Dura Mater																					
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																					
	f. Fascia																					
	g. Heart Valve																					
	h. Ligament																					
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																					
	j. Pericardium																					
5. ENTER CORRECTIONS TO ITEM 4	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																					
	l. Sclera																					
	m. Semen <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous	X	X		X	X	X	X	X	X	X											
	n. Skin																					
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) International Cryogenics, Inc. Attn: Kara L. Denham 32121 Woodward Ave Suite 205 Royal Oak, Michigan 48073  a. PHONE 248-397-8449 EXT _____ b. PHONE _____	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																					
	p. Tendon																					
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																					
	r. Vascular Graft																					
7. ENTER CORRECTIONS TO ITEM 6	s.																					
	t.																					
	u.																					
	v.																					
8. U.S. AGENT  a. E-MAIL _____																						
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Kara L. Denham b. E-MAIL iciinfo@sbcglobal.net c. TITLE Laboratory Director d. DATE 16-NOV-2016																						