

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: 3000718308	<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 VALIDATED BY FDA:03-DEC-2016 DISTRICT: San Francisco PRINTED BY FDA:15-DEC-2016
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION									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)
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps												
	Types of HCT / Ps	Establishment Functions											
		Recover	Screen	Test	Package	Process	Store	Label	Distribute				
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) DCI Donor Services dba Sierra Donor Services  3940 Industrial Blvd. West Sacramento, California 95691  a. PHONE 916-567-1600 EXT _____ b. <input checked="" type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 1000307504) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone	X	X								X		
	b. Cartilage	X	X								X		
	c. Cornea	X	X	X	X	X	X	X	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		
	g. Heart Valve	X	X								X		
	h. Ligament	X	X								X		
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	j. Pericardium	X	X								X		
k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
l. Sclera	X	X	X	X	X	X	X	X	X	X			
m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
5. ENTER CORRECTIONS TO ITEM 4	n. Skin	X	X				X			X			
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Sierra Donor Services Attn: Kristen Pereira, BS, CTBS, CEPT, CQA 3940 Industrial Blvd. West Sacramento, California 95691  a. PHONE 916-567-1600 EXT _____	p. Tendon	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			
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	s.												
	t.												
	u.												
	v.												
8. U.S. AGENT  a. E-MAIL _____	9. REPORTING OFFICIAL'S SIGNATURE												
	a. TYPED NAME Kristen Pereira, BS, CTBS, CEPT, CQA												
	b. E-MAIL kpereira@dcids.org												
	c. TITLE Manager of Quality and Compliance d. DATE 02-DEC-2016												