

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) (See reverse side for instructions)	1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3002813078	2. REASON FOR SUBMISSION 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:19-NOV-2014 DISTRICT: Seattle PRINTED BY FDA:04-DEC-2014
---	--	--	--

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					
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute	Establishment Functions								
a. BLOOD FDA 2830 NO. FEI: 3002813078 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	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																	
	k. Peripheral Blood Stem <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic	X			X	X	X	X	X	X	X						X	
	l. Sclera																	
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																	
	n. Skin																	
	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 checked="" type="checkbox"/> Allogeneic							X	X	X	X	X					X	
	r. Vascular Graft																	
	s. Therapeutic Cells	X			X	X	X	X	X	X	X						X	
	t.																	
	u.																	
	v.																	

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)**
(See reverse side for instructions)

1. REGISTRATION NUMBER
(FDA Establishment Identifier)

FEI: 3002813078

2

ADDITIONAL INFORMATION:

Change made to reporting official

Proprietary Name(s):