

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) <i>(See reverse side for instructions)</i>	1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 3001617760	2. REASON FOR SUBMISSION 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	VALIDATION--FOR FDA USE ONLY 1 VALIDATED BY FDA:02-JUN-2010 DISTRICT: Seattle PRINTED BY FDA:02-JUN-2010
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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				
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	a. Bone	X		X	X	X	X	X	X	X			
	b. Cartilage	X		X	X	X	X	X	X	X			
	c. Cornea												
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Puget Sound Blood Center & Program, dba Northwest Tissue Services 501 Southwest 39th Renton, Washington 98057 a. PHONE 206-292-1879 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	d. Dura Mater												
	e. Embryo												
	f. Fascia	X		X	X	X	X	X	X	X			
	g. Heart Valve	X		X	X	X	X	X	X	X			
5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Puget Sound Blood Center 921 Terry Avenue Attn: Thomas Price, MD Seattle, Washington 98104 a. PHONE 206-292-4172 EXT _____	h. Ligament	X		X	X	X	X	X	X	X			
	i. Oocyte												
	j. Pericardium												
	k. Peripheral Blood Stem Cells					X					X	X	
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	l. Sclera												
	m. Semen												
	n. Skin	X		X	X	X	X	X	X	X			
8. U.S. AGENT a. E-MAIL _____	o. Somatic Cell Therapy Products												
	p. Tendon	X		X	X	X	X	X	X	X			
	q. Umbilical Cord Blood Stem Cells					X					X	X	
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Carol S. Anderson, BA, MT(ASCP) b. E-MAIL Carola@psbc.org c. TITLE Regulatory Affairs Specialist d. DATE 19-MAY-2010	r. Vascular Graft	X		X	X	X	X	X	X	X			
	s. Amniotic Membrane			X	X	X	X	X	X	X			
	t.												
	u.												
	v.												