

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: 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 VALIDATED BY FDA:31-MAR-2017 DISTRICT: Seattle PRINTED BY FDA:20-APR-2017
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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 OFK 121.10	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) Bloodworks 701 Southwest 39th St Renton, Washington 98057 a. PHONE 206-292-6500 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone			X						X							
	b. Cartilage			X						X							
	c. Cornea			X						X							
	d. Dura Mater																
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
	f. Fascia			X							X						
	g. Heart Valve			X							X						
	h. Ligament			X							X						
	i. Oocyte <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous				X						X						
	j. Pericardium				X						X						
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Bloodworks Northwest Attn: QA/RA Department 921 Terry Ave Seattle, Washington 98104 a. PHONE 206-292-6500 EXT _____	k. Peripheral Blood Stem <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic			X						X		X					
	l. Sclera			X						X							
	m. Semen <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous				X						X						
	n. Skin			X						X							
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																
	p. Tendon			X							X						
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic				X						X		X				
	r. Vascular Graft			X							X						
	s. Nerve Tissue			X							X						
	t. Therapeutic Cells			X							X		X				
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Lisa R. Upshaw, MS, CMQ/OE(ASQ) b. E-MAIL lisau@BloodworksNW.Org c. TITLE Regulatory and Compliance Manager d. DATE 30-MAR-2017	u.																
	v.																