


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: 1000307349	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:24-MAY-2017 DISTRICT: Seattle PRINTED BY FDA:21-JUN-2017
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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												
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	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) Life Alaska Donor Services 235 East 8th Avenue Suite 100 Anchorage, Alaska 99501 a. PHONE 907-562-5433 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				X		X	X		
		b. Cartilage	X	X			X		X	X			
		c. Cornea	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		X	X			
		g. Heart Valve	X	X						X			
5. ENTER CORRECTIONS TO ITEM 4		h. Ligament	X	X			X		X	X			
		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Life Alaska Donor Services Attn: George McCann, MD 235 East 8th Avenue Suite 100 Anchorage, Alaska 99501 a. PHONE 907-562-5433 EXT _____		j. Pericardium	X	X			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			
		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____		n. Skin	X	X			X		X	X			
		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
8. U.S. AGENT		p. Tendon	X	X			X		X	X			
		q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
a. E-MAIL		r. Vascular Graft	X	X						X			
9. REPORTING OFFICIAL'S SIGNATURE 		s. Amniotic Membrane	X	X			X			X			
a. TYPED NAME George McCann, MD		t. Placenta	X	X			X			X			
b. E-MAIL georgem@lifealaska.org		u. Amniotic Fluid	X	X			X			X			
c. TITLE President & Chief Executive Officer		v. Umbilical Cord	X	X			X			X			
d. DATE 23-MAY-2017													