


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 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:24-NOV-2016 DISTRICT: Seattle PRINTED BY FDA:15-DEC-2016		
PART I - ESTABLISHMENT INFORMATION 3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	PART II - PRODUCT INFORMATION 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	14. PROPRIETARY NAME(S)
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	Establishment Functions			14. PROPRIETARY NAME(S)	
5. ENTER CORRECTIONS TO ITEM 4	a. Bone <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Screen <input type="checkbox"/> Test <input type="checkbox"/> Package <input type="checkbox"/> Process <input checked="" type="checkbox"/> Store <input type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute b. Cartilage <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Screen <input type="checkbox"/> Test <input type="checkbox"/> Package <input type="checkbox"/> Process <input checked="" type="checkbox"/> Store <input type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute c. Cornea <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Screen <input type="checkbox"/> Test <input type="checkbox"/> Package <input type="checkbox"/> Process <input type="checkbox"/> Store <input type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute d. Dura Mater e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous f. Fascia <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Screen <input type="checkbox"/> Test <input type="checkbox"/> Package <input type="checkbox"/> Process <input checked="" type="checkbox"/> Store <input type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute g. Heart Valve <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Screen <input type="checkbox"/> Test <input type="checkbox"/> Package <input type="checkbox"/> Process <input type="checkbox"/> Store <input type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute h. Ligament <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Screen <input type="checkbox"/> Test <input type="checkbox"/> Package <input type="checkbox"/> Process <input checked="" type="checkbox"/> Store <input type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous j. Pericardium <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Screen <input type="checkbox"/> Test <input type="checkbox"/> Package <input type="checkbox"/> Process <input checked="" type="checkbox"/> Store <input type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic l. Sclera <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Screen <input type="checkbox"/> Test <input type="checkbox"/> Package <input type="checkbox"/> Process <input checked="" type="checkbox"/> Store <input type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous n. Skin <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Screen <input type="checkbox"/> Test <input type="checkbox"/> Package <input type="checkbox"/> Process <input checked="" type="checkbox"/> Store <input type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic p. Tendon <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Screen <input type="checkbox"/> Test <input type="checkbox"/> Package <input type="checkbox"/> Process <input checked="" type="checkbox"/> Store <input type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic r. Vascular Graft <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Screen <input type="checkbox"/> Test <input type="checkbox"/> Package <input type="checkbox"/> Process <input type="checkbox"/> Store <input type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute	s. t. u. v.			
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 _____	7. ENTER CORRECTIONS TO ITEM 6			b. PHONE _____	
8. U.S. AGENT a. E-MAIL _____	9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME George McCann, MD b. E-MAIL georgem@lifealaska.org c. TITLE President & Chief Executive Officer d. DATE 23-NOV-2016			s. t. u. v.	