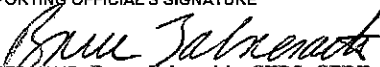


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) <i>(See reverse side for instructions)</i>	1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 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 1 *1000307349* VALIDATED By FDA:12/03/07 PRINTED By FDA:12/07/07 DISTRICT: Seattle
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION		14. PROPRIETARY NAME(S)																																																																																																																																																																																																																																																																																																																																																																																
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2" style="width:30%;">Types of HCT / Ps</th> <th colspan="8" style="text-align: center;">Establishment Functions</th> <th rowspan="2" style="width:5%;">11. HCT/PS DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2" style="width:5%;">12. HCT/PS REGULATED AS MEDICAL DEVICES</th> <th rowspan="2" style="width:5%;">13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> </tr> </thead> <tbody> <tr> <td colspan="12" style="text-align: center;">No HCT / P Specified</td> </tr> <tr><td>a. Bone</td><td>X</td><td>X</td><td></td><td></td><td></td><td>X</td><td></td><td></td><td>X</td><td></td><td></td></tr> <tr><td>b. Cartilage</td><td>X</td><td>X</td><td></td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td></td></tr> <tr><td>c. Cornea</td><td>X</td><td>X</td><td></td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td></td></tr> <tr><td>d. Dura Mater</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>e. Embryo</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td></td> <td colspan="11"> <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous </td> </tr> <tr><td>f. Fascia</td><td>X</td><td>X</td><td></td><td></td><td></td><td>X</td><td></td><td></td><td>X</td><td>X</td><td></td></tr> <tr><td>g. Heart Valve</td><td>X</td><td>X</td><td></td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td></td></tr> <tr><td>h. Ligament</td><td>X</td><td>X</td><td></td><td></td><td></td><td>X</td><td></td><td></td><td>X</td><td>X</td><td></td></tr> <tr><td>i. Oocyte</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td></td> <td colspan="11"> <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous </td> </tr> <tr><td>j. Pericardium</td><td>X</td><td>X</td><td></td><td></td><td></td><td>X</td><td></td><td></td><td>X</td><td>X</td><td></td></tr> <tr><td>k. Peripheral Blood Stem Cells</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr> <td></td> <td colspan="11"> <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic </td> </tr> <tr><td>l. 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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																																																																																																																																																																																																																																																																																																																																																																																			
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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: Bruce Zalneraitis, CTBS, CEBT 235 East 8th Avenue Suite 100 Anchorage, Alaska 99501 a. PHONE 907-562-5433 EXT _____																																																																																																																																																																																																																																																																																																																																																																																			
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9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Bruce Zalneraitis, CTBS, CEBT b. E-MAIL brucez@lifealaska.org c. TITLE Chief Executive Officer d. DATE 26-NOV-2007																																																																																																																																																																																																																																																																																																																																																																																			