

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: 1000523928	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 VALIDATED BY FDA:08-DEC-2011 DISTRICT: Seattle PRINTED BY FDA:15-DEC-2011
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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 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">11. HCT/PS DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2">12. HCT/PS REGULATED AS MEDICAL DEVICES</th> <th rowspan="2">13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> <th rowspan="2">14. PROPRIETARY NAME(S)</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> </table>					Types of HCT / Ps	Establishment Functions								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)	Recover	Screen	Test	Package	Process	Store	Label	Distribute																																																																						
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4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> Community Blood Center dba Community Tissue Services 16361 NE Cameron Blvd. Portland, Oregon 97230 a. PHONE 503-408-9394 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>a. Bone</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>b. Cartilage</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>c. Cornea</td> <td></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>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> <td></td> </tr> <tr> <td>e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></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>f. Fascia</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> </table>					a. Bone	X	X				X	X	X	X				b. Cartilage	X	X				X	X	X	X				c. Cornea													d. Dura Mater													e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													f. Fascia	X	X				X	X	X	X																
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9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME David M. Smith, MD b. E-MAIL dsmith@cbccts.org c. TITLE CEO d. DATE 07-DEC-2011																																																																																																