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| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>PUBLIC HEALTH SERVICE<br>FOOD AND DRUG ADMINISTRATION<br><b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,<br/>                 AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b><br>(See reverse side for instructions) | <b>1. REGISTRATION NUMBER</b><br>(FDA Establishment Identifier)<br><br>FEI: 0003071347 | <b>2. REASON FOR SUBMISSION</b><br>a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING<br>b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING<br>c. <input type="checkbox"/> CHANGE IN INFORMATION<br>d. <input type="checkbox"/> INACTIVE | <b>VALIDATION--FOR FDA USE ONLY</b><br>VALIDATED BY FDA:29-DEC-2017<br>DISTRICT: Seattle<br>PRINTED BY FDA:27-JAN-2018 |
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| PART I - ESTABLISHMENT INFORMATION   | PART II - PRODUCT INFORMATION  | 11. HCT/Ps DESCRIBED IN 21 OF 171.10 | 12. HCT/Ps REGULATED AS MEDICAL DEVICES | 13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS | 14. PROPRIETARY NAME(S) |                   |                         |            |  |  |  |  |  |  |  |  |  |  |  |         |        |      |         |         |       |       |            |
|--|--|--------------------------------------|---|---|-------------------------|-------------------|-------------------------|------------|--|--|--|--|--|--|--|--|--|--|--|---------|--------|------|---------|---------|-------|-------|------------|
| <b>3. OTHER FDA REGISTRATIONS</b><br>a. BLOOD FDA 2830 NO. _____<br>b. DEVICES FDA 2891 NO. _____<br>c. DRUG FDA 2656 NO. _____  | <b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b><br><table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2" style="width:30%;">Types of HCT / Ps</th> <th colspan="9" style="text-align: center;">Establishment Functions</th> <th rowspan="2"></th> <th rowspan="2"></th> <th rowspan="2"></th> <th rowspan="2"></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 |            |  |  |  |  |  |  |  |  |  |  |  | Recover | Screen | Test | Package | Process | Store | Label | Distribute |
| Types of HCT / Ps  | Establishment Functions  |                                      |   |   |                         |                   |                         |            |  |  |  |  |  |  |  |  |  |  |  |         |        |      |         |         |       |       |            |
|  | Recover  | Screen                               | Test                                    | Package   | Process                 | Store             | Label                   | Distribute |  |  |  |  |  |  |  |  |  |  |  |         |        |      |         |         |       |       |            |
| <b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code)<br>Bloodworks<br><br>921 Terry Avenue<br>Seattle, Washington 98104<br><br>a. PHONE 206-292-6500 EXT _____<br>b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT<br>(MANUFACTURING ESTABLISHMENT FEI NO. _____)<br>c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY | a. Bone<br>b. Cartilage<br>c. Cornea<br>d. Dura Mater<br>e. Embryo<br><input type="checkbox"/> SIP<br><input type="checkbox"/> Directed<br><input type="checkbox"/> Anonymous<br>f. Fascia<br>g. Heart Valve<br>h. Ligament<br>i. Oocyte<br><input type="checkbox"/> SIP<br><input type="checkbox"/> Directed<br><input type="checkbox"/> Anonymous<br>j. Pericardium<br>k. Peripheral Blood Stem<br><input checked="" type="checkbox"/> Autologous<br><input checked="" type="checkbox"/> Family Related<br><input checked="" type="checkbox"/> Allogeneic<br>l. Sclera<br>m. Semen<br><input type="checkbox"/> SIP<br><input type="checkbox"/> Directed<br><input type="checkbox"/> Anonymous<br>n. Skin<br>o. Somatic Cell Therapy Products<br><input type="checkbox"/> Autologous<br><input type="checkbox"/> Family Related<br><input type="checkbox"/> Allogeneic<br>p. Tendon<br>q. Umbilical Cord Blood<br><input checked="" type="checkbox"/> Autologous<br><input checked="" type="checkbox"/> Family Related<br><input checked="" type="checkbox"/> Allogeneic<br>r. Vascular Graft |                                      |   |   |                         |                   |                         |            |  |  |  |  |  |  |  |  |  |  |  |         |        |      |         |         |       |       |            |
| <b>5. ENTER CORRECTIONS TO ITEM 4</b>  | s. Therapeutic Cells<br>t. Umbilical Cord<br>u.<br>v.  |                                      |   |   |                         |                   |                         |            |  |  |  |  |  |  |  |  |  |  |  |         |        |      |         |         |       |       |            |
| <b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code)<br>Bloodworks<br>Attn: Lisa R. Upshaw, MS, CMQ/OE(ASQ)<br>QA/RA Department<br>921 Terry Ave<br>Seattle, Washington 98104<br><br>a. PHONE 206-292-6500 EXT _____  | <b>7. ENTER CORRECTIONS TO ITEM 6</b><br>b. PHONE _____  |                                      |   |   |                         |                   |                         |            |  |  |  |  |  |  |  |  |  |  |  |         |        |      |         |         |       |       |            |
| <b>8. U.S. AGENT</b><br><br>a. E-MAIL _____  | <b>9. REPORTING OFFICIAL'S SIGNATURE</b><br><br>a. TYPED NAME Lisa R. Upshaw, MS, CMQ/OE(ASQ)<br>b. E-MAIL Regulatory@BloodworksNW.Org<br>c. TITLE Regulatory and Compliance Manager<br>d. DATE 28-DEC-2017  |                                      |   |   |                         |                   |                         |            |  |  |  |  |  |  |  |  |  |  |  |         |        |      |         |         |       |       |            |