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| 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: 3003567004 | 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:09-DEC-2011 DISTRICT: Florida 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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| | Recover | Screen | Test | Package | Process | Store | Label | Distribute | | | | | | | | | | | | | | | | | | |
| 4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> Southeast Tissue Alliance, Inc. 1901 NW 67th Place Bay D Gainesville, Florida 32653 a. PHONE 352-271-7300 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 | | | | | | | | | | | | | | | | |
| | b. Cartilage | 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 | | | | | | | | | | | | | | | | |
| | g. Heart Valve | X | | | | | X | X | | X | | | | | | | | | | | | | | | | |
| | h. Ligament | X | | | | | X | X | | X | | | | | | | | | | | | | | | | |
| | i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | | | | | | | | | | | | | |
| | j. Pericardium | X | | | | | X | X | | X | | | | | | | | | | | | | | | | |
| 6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> Southeast Tissue Alliance, Inc. Attn: Lawrence Hopkins 6241 NW 23rd. St. Suite 400 Gainesville, Florida 32653 a. PHONE 352-416-6641 EXT _____ b. PHONE _____ | k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | | | | | | | | | | | | | |
| | l. Sclera | | | | | | | | | | | | | | | | | | | | | | | | | |
| | m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | | | | | | | | | | | | | |
| | n. Skin | X | | | | | X | X | | X | | | | | | | | | | | | | | | | |
| | o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | | | | | | | | | | | | | |
| | p. Tendon | X | | | | | X | X | | X | | | | | | | | | | | | | | | | |
| | q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | | | | | | | | | | | | | |
| | r. Vascular Graft | X | | | | | X | X | | X | | | | | | | | | | | | | | | | |
| | s. Nerve Tissue | X | | | | | X | X | | X | | | | | | | | | | | | | | | | |
| | t. Placenta | X | | | | | X | X | | X | | | | | | | | | | | | | | | | |
| 9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Lawrence Hopkins b. E-MAIL lagle@donorcare.org c. TITLE Chief Executive Officer d. DATE 08-DEC-2011 | u. | | | | | | | | | | | | | | | | | | | | | | | | | |
| | v. | | | | | | | | | | | | | | | | | | | | | | | | | |