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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) (See reverse side for instructions) | 1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3002708768 | 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:16-NOV-2017 DISTRICT: Florida PRINTED BY FDA:20-DEC-2017 |
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| PART I - ESTABLISHMENT INFORMATION | PART II - PRODUCT INFORMATION | | | | | | | | | | | | |
|--|--|---------|--------|------|---------|---------|-------|-------|------------|--------------------------------------|---|---|-------------------------|
| 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 | | | | | | | | | | | | |
| 4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Lions Eye Institute for Transplant and Research, Inc 8515 Baymeadows Way Suite 303 Jacksonville, Florida 32256 a. PHONE 813-289-1200 EXT _____ b. <input checked="" type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3000206983) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY | Establishment Functions | | | | | | | | | | | | |
| 5. ENTER CORRECTIONS TO ITEM 4 | Types of HCT / Ps | Recover | Screen | Test | Package | Process | Store | Label | Distribute | 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) |
| 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Lions Eye Institute for Transplant & Research Attn: Mikelanne Schipper, CEBT 1410 N. 21st Street Tampa, Florida 33605 a. PHONE 813-289-1200 EXT _____ | a. Bone | | | | | | | | | | | | |
| 7. ENTER CORRECTIONS TO ITEM 6 a. PHONE _____ b. PHONE _____ | b. Cartilage | | | | | | | | | | | | |
| 8. U.S. AGENT a. E-MAIL _____ | c. Cornea | X | | | X | | | X | | X | | | |
| 9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Mikelanne Schipper, CEBT b. E-MAIL mschipper@lionseyeinstitute.org c. TITLE Director of Quality & Regulatory Affairs d. DATE 16-NOV-2017 | d. Dura Mater | | | | | | | | | | | | |
| | e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | |
| | f. Fascia | | | | | | | | | | | | |
| | g. Heart Valve | | | | | | | | | | | | |
| | h. Ligament | | | | | | | | | | | | |
| | i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | |
| | j. Pericardium | | | | | | | | | | | | |
| | k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | |
| | l. Sclera | X | | | X | | | X | | X | | | |
| | m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | |
| | n. Skin | | | | | | | | | | | | |
| | o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | |
| | p. Tendon | | | | | | | | | | | | |
| | q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | |
| | r. Vascular Graft | | | | | | | | | | | | |
| | s. | | | | | | | | | | | | |
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