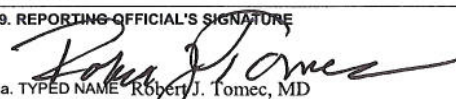


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|---|--|--|--|--|------|---------|---------|-------|--|---|--|----------------------------|
| DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) <i>(See reverse side for instructions)</i> | | 1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 0001870308 | 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:18-NOV-2011 DISTRICT: Detroit PRINTED BY FDA:23-NOV-2011 | | | | | | | | |
| 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. FEI: 0001870308 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____ | | 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps | | | | | | | | | | |
| | | Establishment Functions | | | | | | | | | | |
| | | Types of HCT / Ps | 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> South Bend Medical Foundation, Inc 530 N. Lafayette Boulevard South Bend, Indiana 46601-1098 a. PHONE 574-234-4716 EXT 1522 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY | | a. Bone | | | X | | | | | | X | |
| | | b. Cartilage | | | X | | | | | | X | |
| | | c. Cornea | | | X | | | | | | X | |
| | | d. Dura Mater | | | | | | | | | | |
| | | e. Embryo | | | | X | | | | | X | |
| | | | | | | | | | | | | |
| | | f. Fascia | | | X | | | | | | X | |
| 5. ENTER CORRECTIONS TO ITEM 4 | | g. Heart Valve | | | X | | | | | | X | |
| | | h. Ligament | | | X | | | | | | X | |
| | | i. Oocyte | | | | X | | | | | X | |
| | | j. Pericardium | | | X | | | | | | X | |
| | | k. Peripheral Blood Stem Cells | | | | | | | | | | |
| | | l. Sclera | | | X | | | | | | X | |
| | | m. Semen | | | | 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> South Bend Medical Foundation, Inc Attn: Robert J. Tomec, MD 530 N. Lafayette Boulevard South Bend, Indiana 46601-1098 a. PHONE 574-234-4176 EXT _____ | | n. Skin | | | X | | | | | | X | |
| | | o. Somatic Cell Therapy Products | | | | | | | | | | |
| 7. ENTER CORRECTIONS TO ITEM 6 | | p. Tendon | | | X | | | | | | X | |
| | | q. Umbilical Cord Blood Stem Cells | | | X | | | | | | | X |
| 8. U.S. AGENT a. E-MAIL _____ | | r. Vascular Graft | | | X | | | | | | X | |
| 9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Robert J. Tomec, MD b. E-MAIL rtomec@smbf.org c. TITLE President | | s. | | | | | | | | | | |
| | | t. | | | | | | | | | | |
| | | u. | | | | | | | | | | |
| d. DATE 17-NOV-2011 | | v. | | | | | | | | | | |