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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 (Field Establishment Identifier) FEI: 3005897621 | 2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE | VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:31-AUG-2011 DISTRICT: Atlanta PRINTED BY FDA:09-SEP-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 | 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps | | | | | | | | | | | | |
| | Types of HCT / Ps | Establishment Functions | | | | | | | | | | | |
| | | Recover | Screen | Test | Package | Process | Store | Label | Distribute | | | | |
| 4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Surgical Biologics, a MiMedx Group Company 60 Chastain Center Blvd. Suite 60-62 Kennesaw, Georgia 30144 | a. Bone | | | | | | | | | | | | |
| | b. Cartilage | | | | | | | | | | | | |
| | c. Cornea | | | | | | | | | | | | |
| a. PHONE 404-461-9265 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY | d. Dura Mater | | | | | | | | | | | | |
| | e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | |
| | f. Fascia | | | | | | | | | | | | |
| 5. ENTER CORRECTIONS TO ITEM 4 | g. Heart Valve | | | | | | | | | | | | |
| | h. Ligament | | | | | | | | | | | | |
| | i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | |
| 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Surgical Biologics LLC Attn: John Daniel 60 Chastain Center Blvd. Suite 60 Kennesaw, Georgia 30144 | j. Pericardium | | | | | | | | | | | | |
| | k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | |
| | l. Sclera | | | | | | | | | | | | |
| a. PHONE 404-461-9267 EXT _____ | m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | |
| | n. Skin | | | | | | | | | | | | |
| 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____ | o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | |
| | p. Tendon | | | | | | | | | | | | |
| 8. U.S. AGENT | q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | |
| | r. Vascular Graft | | | | | | | | | | | | |
| 9. REPORTING OFFICIAL'S SIGNATURE | s. Amniotic Membrane | X | X | | X | X | X | X | X | X | | *** See full text on next page | |
| | t. | | | | | | | | | | | | |
| | u. | | | | | | | | | | | | |
| | v. | | | | | | | | | | | | |
| | a. TYPED NAME John Daniel b. E-MAIL jdaniel@surgicalbio.com c. TITLE President | d. DATE 30-AUG-2011 | | | | | | | | | | | |

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
(Field Establishment Identifier)

FEI: 3005897621

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ADDITIONAL INFORMATION:

Additional Proprietary Names: AmBioChoice Plus

Proprietary Name(s):

. Amniotic AmbioDry2, Ambio5, EpiFix, BioCover, BioXclude,
Membrane AmnioClear, BioArthro, NuShield, AmnioShield,
 AmnioFix, AmBioChoice