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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: 3004976934 | 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-DEC-2014 DISTRICT: Detroit PRINTED BY FDA:22-DEC-2014 |
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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 | 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) Cook General BioTechnology, LLC 1102 Indiana Ave. Indianapolis, Indiana 46202 a. PHONE 317-917-3450 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY | a. Bone | | | | | | | | | | | | | |
| | b. Cartilage | | | | | | | | | | | | | |
| | c. Cornea | | | | | | | | | | | | | |
| | 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 | | | | | | | | | | | | | |
| 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Cook General BioTechnology, LLC Attn: Amelia E. Hufford, PhD 1102 Indiana Ave. Indianapolis, Indiana 46202 a. PHONE 317-917-3450 EXT _____ b. PHONE _____ | k. Peripheral Blood Stem <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | X | | X | X | X | X | | | | |
| | l. Sclera | | | | | | | | | | | | | |
| | m. Semen <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous | | | | X | | X | X | X | X | | | | |
| | n. Skin | | | | | | | | | | | | | |
| | o. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic | X | X | | X | X | X | X | X | X | | X | | |
| | p. Tendon | | | | | | | | | | | | | |
| | q. Umbilical Cord Blood <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | X | X | | X | X | X | X | X | X | | | | |
| | r. Vascular Graft | | | | | | | | | | | | | |
| | s. Placenta | X | X | | X | X | X | X | X | X | | | | |
| | t. Tooth Pulp | X | | | X | X | X | X | X | X | | | | |
| u. Umbilical Cord | X | X | | X | X | X | X | X | X | | | | | |
| v. | | | | | | | | | | | | | | |

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: 3004976934

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ADDITIONAL INFORMATION:

Somatic cell therapy products include mesenchymal stem cells (MSC) from multiple sources, for example, cord tissue MSC, Dental Pulp MSC and bone marrow MSC. Somatic cell therapy products are released or will be released under IND, as required.

Proprietary Name(s):