See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017

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: 3012448339

**2. REASON FOR SUBMISSION**

a. ☐ INITIAL REGISTRATION / LISTING
b. ☒ ANNUAL REGISTRATION / LISTING
c. ☐ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:17-MAR-2017
DISTRICT: San Francisco
PRINTED BY FDA:20-MAR-2017

## PART I - ESTABLISHMENT INFORMATION

**3. OTHER FDA REGISTRATIONS**

a. BLOOD FDA 2830 NO.
b. DEVICES FDA 2891 NO. FEI: 3012448339
c. DRUG FDA 2656 NO. FEI: 3012448339

**4. PHYSICAL LOCATION** (Include legal name, number and street, city, state, country, and post office code)

Smart World LLC dba Steri-Tek

48225 Lakeview Blvd
Fremont, California 94538

a. PHONE 510-933-9700 EXT
b. ☐ SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO._____
c. ☐ TESTING FOR MICRO-ORGANISMS ONLY

**5. ENTER CORRECTIONS TO ITEM 4**

**6. MAILING ADDRESS OF REPORTING OFFICIAL** (Include institution name if applicable, number and street, city, state, country, and post office code)

Smart World LLC dba Steri-Tek
Attn: Sasan Amirgholizadeh
48225 Lakeview Blvd
Fremont, California 94538

a. PHONE 510-933-9700 EXT

**7. ENTER CORRECTIONS TO ITEM 6** b. PHONE

**8. U.S. AGENT**

a. E-MAIL

**9. REPORTING OFFICIAL'S SIGNATURE**

a. TYPED NAME Sasan Amirgholizadeh
b. E-MAIL sasana@steri-tek.com
c. TITLE Quality Manager d. DATE 16-MAR-2017

## PART II - PRODUCT INFORMATION

**10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps**

| Types of HCT / Ps | Establishment Functions: Recover | Screen | Test | Package | Process | Store | Label | Distribute | 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) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| a. Bone | | | | | | | | | | | | |
| b. Cartilage | | | | | | | | | | | | |
| c. Cornea | | | | | X | X | X | X | X | | | |
| d. Dura Mater | | | | | | | | | | | | |
| e. Embryo ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| f. Fascia | | | | | | | | | | | | |
| g. Heart Valve | | | | | | | | | | | | |
| h. Ligament | | | | | | | | | | | | |
| i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| j. Pericardium | | | | | X | X | X | X | X | | | |
| k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| l. Sclera | | | | | X | X | X | X | X | | | |
| m. Semen ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| n. Skin | | | | | | | | | | | | |
| o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| p. Tendon | | | | | | | | | | | | |
| q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| r. Vascular Graft | | | | | | | | | | | | |
| s. | | | | | | | | | | | | |
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