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: 3010664398

**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:22-DEC-2016
DISTRICT: Los Angeles
PRINTED BY FDA:28-DEC-2016

## PART I - ESTABLISHMENT INFORMATION

**3. OTHER FDA REGISTRATIONS**
a. BLOOD FDA 2830 NO. _____
b. DEVICES FDA 2891 NO. _____
c. DRUG FDA 2656 NO. _____

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

850 Health Sciences Road
Suite 2020
Irvine, California 92617

a. PHONE (949) 854-0800 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)
SightLife
Attn: Thomas D. Miller, B.S. CEBT
1200 6th Ave
Ste 300
Seattle, Washington 98101

a. PHONE 206-838-4630 EXT

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

**8. U.S. AGENT**

a. E-MAIL

**9. REPORTING OFFICIAL'S SIGNATURE**
Thomas D. Miller
a. TYPED NAME Thomas D. Miller, B.S. CEBT
b. E-MAIL tom.miller@sightlife.org
c. TITLE VP of Quality and Regulatory Affairs d. DATE 21-DEC-2016

## 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 | X | X | X | | | |
| d. Dura Mater | | | | | | | | | | | | |
| e. Embryo ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| f. Fascia | | | | | | X | | X | X | | | TUTOPLAST |
| g. Heart Valve | | | | | | | | | | | | |
| h. Ligament | | | | | | | | | | | | |
| i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| j. Pericardium | | | | | | | | | | | | |
| k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| l. Sclera | X | X | | X | X | X | X | X | X | | | |
| m. Semen ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| n. Skin | | | | | | X | | X | X | | | FlexHD Structural |
| o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| p. Tendon | | | | | | | | | | | | |
| q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| r. Vascular Graft | | | | | | | | | | | | |
| s. Amniotic Membrane | | | | | | X | | X | X | | | AmnioGraft, PROKERA |
| t. | | | | | | | | | | | | |
| u. | | | | | | | | | | | | |
| v. | | | | | | | | | | | | |