

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: 3003368882

**2. REASON FOR SUBMISSION**  
 a.  INITIAL REGISTRATION / LISTING  
 b.  ANNUAL REGISTRATION / LISTING  
 c.  CHANGE IN INFORMATION  
 d.  INACTIVE

VALIDATION—FOR FDA USE ONLY  
 VALIDATED BY FDA: 20-DEC-2017  
 DISTRICT: Philadelphia  
 PRINTED BY FDA: 27-JAN-2018

PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION										14. PROPRIETARY NAME(S)						
3. OTHER FDA REGISTRATIONS		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps										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		
		Establishment Functions																
		Types of HCT / Ps		Recover	Screen	Test	Package	Process	Store	Label	Distribute							
a. BLOOD FDA 2830 NO. _____		a. Bone																
b. DEVICES FDA 2891 NO. _____		b. Cartilage																
c. DRUG FDA 2656 NO. _____		c. Cornea		X			X	X	X	X	X							
		d. Dura Mater																
		e. Embryo																
		f. Fascia																
		g. Heart Valve																
		h. Ligament																
		i. Oocyte																
		j. Pericardium																
		k. Peripheral Blood Stem																
		l. Sclera		X			X	X	X	X	X							
		m. Semen																
		n. Skin																
		o. Somatic Cell Therapy Products																
		p. Tendon																
		q. Umbilical Cord Blood																
		r. Vascular Graft																
		s.																
		t.																
		u.																
		v.																

**4. PHYSICAL LOCATION** (include legal name, number and street, city, state, country, and post office code)  
 SightLife (also dba SightLife Surgical Inc.)  
 2346 Jacksonville Road  
 Bethlehem, Pennsylvania 18017

a. PHONE 610-625-3800 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, MS, CEFT  
 1200 6th Ave  
 Ste 300  
 Seattle, Washington 98101

a. PHONE 206-838-4630 EXT \_\_\_\_\_  
 b. PHONE \_\_\_\_\_

**7. ENTER CORRECTIONS TO ITEM 6**

**8. U.S. AGENT**

a. E-MAIL \_\_\_\_\_

**9. REPORTING OFFICIAL'S SIGNATURE**  
 Thomas D. Miller  
 Thomas D. Miller, MS, CEFT  
 tom.miller@sightlifesurgical.com  
 1/29/2018  
 d. DATE 19-DEC-2017

**FORM FDA - 3356 (7/17)**