

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: 3005357288

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:21-DEC-2017
 DISTRICT: Atlanta
 PRINTED BY FDA:27-JAN-2018

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
 a. BLOOD FDA 2830 NO. _____
 b. DEVICES FDA 2891 NO. FEI: 3005357288
 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.)
 101 North Chestnut Street
 Suite 303
 Winston-Salem, North Carolina 27101

a. PHONE 336-784-4603 EXT _____
 b. SATELLITE RECOVERY ESTABLISHMENT
 MANUFACTURING ESTABLISHMENT FEI NO. _____
 c. TESTING FOR MICRO-ORGANISMS ONLY

5. ENTER CORRECTIONS TO ITEM 4

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS

Types of HCT / Ps	Establishment Functions						14. PROPRIETARY NAME(S)					
	Recover	Screen	Test	Package	Process	Store		Label	Distribute			
a. Bone												
b. Cartilage												
c. Cornea				X	X	X	X	X	X	X		
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												
k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
l. Sclera												
m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
n. Skin												
o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
p. Tendon												
q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
r. Vascular Graft												
s.												
t.												
u.												
v.												

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

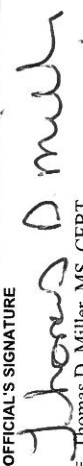
6. MAILING ADDRESS OF REPORTING OFFICIAL (include institution name if applicable, number and street, city, state, country, and post office code)
 SightLife (also dba SightLife Surgical Inc.)
 Attn: Thomas D. Miller, MS, CEBT
 101 North Chestnut Street
 Suite 303
 Winston-Salem, North Carolina 27101

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, CEBT
 tom.miller@sightlifesurgical.com
 1/29/2018

a. TYPED NAME
 b. E-MAIL
 c. TITLE VP of Quality and Regulatory Affairs
 d. DATE 21-DEC-2017