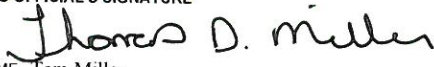


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) (See reverse side for instructions)		1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3003368882	2. REASON FOR SUBMISSION a. <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:22-DEC-2016 DISTRICT: Philadelphia 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. _____		PART II - PRODUCT INFORMATION 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	14. PROPRIETARY NAME(S)			
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. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		Establishment Functions											
		Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store			Label	Distribute	
		a. Bone											
		b. Cartilage											
		c. Cornea	X	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	X	X		X	X	X	X	X	X				
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.													
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: Tom Miller 1200 6th Ave Ste 300 Seattle, Washington 98101 a. PHONE 206-838-4630 EXT _____													
7. ENTER CORRECTIONS TO ITEM 6													
8. U.S. AGENT a. E-MAIL _____													
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Tom Miller b. E-MAIL tom.miller@sightlife.org c. TITLE VP Quality Assurance/Regulatory Affairs d. DATE 21-DEC-2016													