

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> (See reverse side for instructions)	<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3008286876	<b>2. REASON FOR SUBMISSION</b> 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	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:21-NOV-2017 DISTRICT: Florida PRINTED BY FDA:27-JAN-2018
---	--	--	--

PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION										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)								
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps																					
	Types of HCT / Ps	Establishment Functions								Recover					Screen	Test	Package	Process	Store	Label	Distribute	
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. FEI: 3008286876 c. DRUG FDA 2656 NO. _____		a. Bone	X	X		X	X	X	X		X	X										
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) LifeLink Tissue Bank  9661 Delaney Creek Boulevard Tampa, Florida 33619  a. PHONE 813-804-4324 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	b. Cartilage	X	X		X	X	X	X	X	X												
	c. Cornea																					
	d. Dura Mater																					
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																					
	f. Fascia	X	X		X	X	X	X	X	X	X											
	g. Heart Valve	X	X																			
	h. Ligament	X	X		X	X	X	X	X	X	X											TruArc
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																					
	j. Pericardium	X	X		X	X	X	X	X	X	X											
	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																						
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) LifeLink Tissue Bank Attn: Elizabeth S. Horn-Brinson, BS 9661 Delaney Creek Boulevard Tampa, Florida 33619  a. PHONE 813-804-4324 EXT _____	n. Skin	X	X																			
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																					
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	p. Tendon	X	X		X	X	X	X	X	X												
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																					
	r. Vascular Graft	X	X																			
8. U.S. AGENT  a. E-MAIL _____	s.																					
	t.																					
	u.																					
	v.																					
	9. REPORTING OFFICIAL'S SIGNATURE																					
a. TYPED NAME Elizabeth S. Horn-Brinson, BS b. E-MAIL liz.brinson@lifelinkfound.org c. TITLE VP, Quality Assurance d. DATE 20-NOV-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: 3008286876

**ADDITIONAL INFORMATION:**

LifeLink of Florida OPO formerly FEI#:3003453640, is also located at this location and has been consolidated into FEI#:3008286876, LifeLink Tissue Bank, Delaney Creek.

Proprietary Names: A. Bone: AlloPure, Allosculpt, Hero, Indux, LifeFlex, LifeGraft, NuFix, Optecure, OsteoAmp, Osteocel Plus, Osteocel Pro, Osteostim, Purebone, Vikos, Vesuvius, SiFix

**Proprietary Name(s):**