

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) <i>(See reverse side for instructions)</i>	1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 3008286876	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 1 VALIDATED BY FDA:23-NOV-2011 DISTRICT: Florida PRINTED BY FDA:02-DEC-2011
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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. _____ c. DRUG FDA 2656 NO. _____	a. Bone		X		X	X	X	X	X	X		*** See full text on next pag	
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> LifeLink Foundation Tissue Bank 9661 Delaney Creek Boulevard Tampa, Florida 33619 a. PHONE 813-886-8111 EXT 7225 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			
	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		
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve		X							X			
	h. Ligament		X		X	X	X			X			
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	j. Pericardium		X		X	X	X			X			
	k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> LifeLink Tissue Bank Attn: Elizabeth S. Horn-Brinson, MT, BS, ASCP 9661 Delaney Creek Boulevard Tampa, Florida 33619 a. PHONE 813-886-8111 EXT 7225	l. Sclera												
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	n. Skin		X							X			
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	p. Tendon		X		X	X	X			X			
	q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
8. U.S. AGENT a. E-MAIL	r. Vascular Graft		X							X			
	s.												
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Elizabeth S. Horn-Brinson, MT, BS, ASCP b. E-MAIL liz.brinson@lifelinkfound.org c. TITLE VP, Quality Assurance d. DATE 22-NOV-2011	t.												
	u.												
	v.												

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
(Field Establishment Identifier)

2

FEI: 3008286876

ADDITIONAL INFORMATION:

Proprietary Name(s):

- a. Bone LifeGraft, Oralife, OsteoStim, AlloTAQ, TruArc,
FacetFuse-Allo, Cross-Fuse Advantage(TLIF),
BigFoot(ALIF), Osteocel Plus