

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: 3001238470	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:21-NOV-2017 DISTRICT: San Juan PRINTED BY FDA:27-JAN-2018
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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											
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	Establishment Functions											
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute			
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Lifelink of Puerto Rico Daimler-Chrysler Bldg./Metro Office Park 1 Calle 1 , Suite 100 Guaynabo, Puerto Rico 00968-1711 a. PHONE 800-558-0977 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone	X	X							X		
	b. Cartilage	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		
	g. Heart Valve	X	X							X		
	h. Ligament	X	X							X		
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
	j. Pericardium	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	n. Skin											
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
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 9661 Delaney Creek Boulevard Tampa, Florida 33619 a. PHONE 813-804-4325 EXT 4325	p. Tendon	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							X		
7. ENTER CORRECTIONS TO ITEM 6 a. PHONE _____ b. PHONE _____	s.											
	t.											
8. U.S. AGENT a. E-MAIL _____	u.											
	v.											
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Elizabeth S. Horn-Brinson b. E-MAIL liz.brinson@lifelinkfound.org c. TITLE VP, QA d. DATE 20-NOV-2017												