

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: 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 1 VALIDATED BY FDA:23-NOV-2011 DISTRICT: San Juan 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 a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2" style="width:30%;">Types of HCT / Ps</th> <th colspan="8" style="text-align: center;">Establishment Functions</th> <th rowspan="2">Recover</th> <th rowspan="2">Screen</th> <th rowspan="2">Test</th> <th rowspan="2">Package</th> <th rowspan="2">Process</th> <th rowspan="2">Store</th> <th rowspan="2">Label</th> <th rowspan="2">Distribute</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> </tr> </thead> </table>	Types of HCT / Ps	Establishment Functions								Recover	Screen	Test	Package	Process	Store	Label	Distribute	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
Types of HCT / Ps	Establishment Functions								Recover	Screen									Test	Package	Process	Store	Label	Distribute						
	Recover	Screen	Test	Package	Process	Store	Label	Distribute																						
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> Lifelink of Puerto Rico Daimler-Chrysler Bldg./Metro Office Park Street 1 # 1, Suite 100 Guaynabo, Puerto Rico 00968-1705 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																											
	b. Cartilage	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																											
	g. Heart Valve	X	X																											
	h. Ligament	X	X																											
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																													
	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: Liz S. Horn-Brinson, MT, BS, ASCP 9661 Delaney Creek Boulevard Tampa, Florida 33619 a. PHONE 813-886-8111 EXT 7225	j. Pericardium	X	X																										
	k. Peripheral Blood Stem Cells <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																													
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	n. Skin																													
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																													
8. U.S. AGENT a. E-MAIL _____	p. Tendon	X	X																											
	q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																													
	r. Vascular Graft	X	X																											
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Liz S. Horn-Brinson, MT, BS, ASCP b. E-MAIL liz.brinson@lifelinkfound.org c. TITLE VP, Quality Assurance d. DATE 22-NOV-2011	s.																													
	t.																													
	u.																													
	v.																													