

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: 3006813973	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:08-JUN-2017 DISTRICT: Philadelphia PRINTED BY FDA:22-JUN-2017
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION															14. PROPRIETARY NAME(S)
3. OTHER FDA REGISTRATIONS	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			
	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) MTF Jessup Distribution Center 1175 Mid Valley Drive Olyphant, Pennsylvania 18447 a. PHONE 570-343-5433 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	X			*** See full text on next page		
	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															
	h. Ligament						X		X	X						
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous															
	j. Pericardium						X		X	X						
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) Musculoskeletal Transplant Foundation Attn: Joel Osborne 125 May Street Suite 300 Edison , New Jersey 08837 a. PHONE 732-661-0202 EXT _____ b. PHONE _____	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															
	n. Skin						X		X	X				*** See full text on next page		
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic															
	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															
	7. ENTER CORRECTIONS TO ITEM 6 8. U.S. AGENT a. E-MAIL _____	s. Amniotic Membrane						X		X	X				*** See full text on next page	
		t. Adipose Tissue						X		X	X					
u.																
v.																
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Joel C. Osborne b. E-MAIL ra_licenses@mtf.org c. TITLE Vice President, RA d. DATE 07-JUN-2017																

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PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
**ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,
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(FDA Establishment Identifier)

FEI: 3006813973

ADDITIONAL INFORMATION:

- A) ENACT, Conform Putty, Conform Cube, Trinity Evolution, Trinity ELITE, DBX, DBX Strip, DBX Inject, AFT, Dental DBX, Luminary PLIF, Cartilage, Allograft Matrix, Prime DBM, Oracle, Incite, Prolix, Profile, AlloQuent
- N) FlexHD Structural Diamond, AlloPatch Pliable, AlloPatchHD, BellaDerm, PerioDerm, FlexHD Pliable MAX, Renuva
- S) Essence

Proprietary Name(s):

- a. Bone DBX Mix, DBX Paste, DBX Putty, Conform Sheet, Luminary CC-ALIF, Luminary T-PLIF, ARCH ODL, VerteFill, Conform Flex,
- n. Skin FlexHD Pliable, FlexHD Pliable Perforated, FlexHD Pliable Shaped, FlexHD Pliable Fenestrated, FlexHD Structural,
- Amniotic AmnioBand SL, AmnioBand Viable, AmnioBand
- Membrane Particulate, AmnioClear, AmnioBand, VersaShield, Revitalon, Enhance, Blockade