

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: 3001236616	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: New Jersey PRINTED BY FDA:21-JUN-2017
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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				
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Musculoskeletal Transplant Foundation Edison Corporate Center 125 May St. Suite 300 Edison, New Jersey 08837 a. PHONE 732-661-0202 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	X	X	X	X	*** See full text on next page	
	b. Cartilage		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			
	g. Heart Valve												
	h. Ligament		X		X	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	X	X			
5. ENTER CORRECTIONS TO ITEM 4	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												
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 Edison Corporate Center 125 May St. Suite 300 Edison, New Jersey 08837 a. PHONE 732-661-0202 EXT _____ b. PHONE _____	n. Skin		X		X	X	X	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												
7. ENTER CORRECTIONS TO ITEM 6	p. Tendon		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												
8. U.S. AGENT a. E-MAIL _____	s. Amniotic Membrane		X		X	X	X	X	X	X		*** See full text on next page	
	t. Adipose Tissue		X		X	X	X	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: 3001236616

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