

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: 3002826851	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: Los Angeles 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					
	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 1795-A Orange Tree Lane Redlands, California 92374 a. PHONE 909-792-7544 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						*** See full text on next page	
	b. Cartilage						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							
	g. Heart Valve																	
	h. Ligament							X	X	X	X							
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																	
	j. Pericardium							X	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 C. 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	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	X								
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																	
	r. Vascular Graft																	
	s. Amniotic Membrane						X	X	X	X							*** See full text on next page	
	t. Adipose Tissue						X	X	X	X								
8. U.S. AGENT a. E-MAIL _____ 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	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)

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(FDA Establishment Identifier)

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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