

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: 3011400049	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:29-NOV-2017 DISTRICT: New York 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												
	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 504 White Spruce Blvd Rochester, New York 14623 a. PHONE 5852727890 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												
	j. Pericardium		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 - Rochester Attn: Joel Osborne 125 May Street Suite 300 Edison, New Jersey 08837 a. PHONE 732-661-0202 EXT _____ 7. ENTER CORRECTIONS TO ITEM 6 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		
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	p. Tendon		X								X		
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	r. Vascular Graft		X								X		
	s. Amniotic Membrane		X								X		
	t. Placenta		X								X		
8. U.S. AGENT a. E-MAIL _____ 9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Joel Osborne b. E-MAIL ra_licenses@mtf.org c. TITLE Vice President, RA d. DATE 29-NOV-2017	u. Adipose Tissue		X							X			
	v.												