See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 6/30/2020

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. ☐ INITIAL REGISTRATION / LISTING
b. ☒ ANNUAL REGISTRATION / LISTING
c. ☐ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:29-NOV-2017
DISTRICT: Los Angeles
PRINTED BY FDA:27-JAN-2018

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. _____

b. DEVICES FDA 2891 NO. _____

c. DRUG FDA 2656 NO. _____

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. ☐ SATELLITE RECOVERY ESTABLISHMENT
(MANUFACTURING ESTABLISHMENT FEI NO._____

c. ☐ TESTING FOR MICRO-ORGANISMS ONLY

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

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

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 29-NOV-2017

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	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)
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 ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia						X	X	X	X			
g. Heart Valve												
h. Ligament						X	X	X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium						X	X	X	X			
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin						X	X	X	X			*** See full text on next page
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon						X	X	X	X			
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft												
s. Amniotic Membrane						X	X	X	X			*** See full text on next page
t. Adipose Tissue						X	X	X	X			
u.												
v.												

FORM FDA - 3356 (7/17)

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ADDITIONAL INFORMATION:

a) ENACT, Conform Putty, Conform Cube, Trinity Evolution, Trinity ELITE, 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	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 Membrane	AmnioBand SL, AmnioBand Viable, AmnioBand Particulate, AmnioClear, AmnioBand, VersaShield, Revitalon, Enhance, Blockade