

OMB Beyanı için Talimatlara bakınız. ONAYLI FORM OMB No.0910-054.3. Son Geçerlilik Tarihi: 31.03.2017

I. SICIL NUMARASI
(FDA Kuruluş Kimlik No.)
FEL:3001236616

SAĞLIK VE BEŞERİ HİZMETLER BAKANLIĞI
HALK SAĞLIĞI MÜDÜRLÜĞÜ
GIDA VE İLAÇ DAİRESİ
İNSAN HÜCRELERİ, DOKULARI VE HÜCRE VE DOKU BAZLI ÜRÜNLER (HCT/PI'ler) İÇİN KURULUŞ
TESCİLİ VE KAYDI
(Talimatlar için arka sayfaya bakınız)

EK BİLGİLER:

Tescilli Adlar:

A. Kemik ENHANCE, DBX Mix, DBX Paste, DBX Putty, Conform Sheet, Luminary CC-ALIP, Luminary T-PLIF,
Luminary PLIF, ARCH ODL, VerteFill, Conform Flex, ENACT

N. Deri: FlexHD Structural Plus, FlexHD Pliable Perforated, FlexHD Structural, AlloPatch Pliable

Tescilli Ad/Adları:

a. Kemik Conform Putty, Conform Cube, Trinity Evolution, Trinity ELITE, DBX, DBX Strip, DBX Inject,
AFT, Allofix, Dental DBX

ii. Deri DernaMatrix, FlexHD, FlexHD Diamond, Allopatch HD, BellaDerm, PerioDerm, FlexHD Pliable

Amniyon Zarf AmnioClear, AmnioBand, Guardian, VersaShield, Revitalon, AmnioBand

FORM FDA 3356 (5/14)

Sayfa: 2

№ 16927



Tercüme edilmek üzere bana verilen İngilizce dilindeki asıl belgeyi, Türkçe diline tam ve doğru olarak çevirdiğimi beyan ederim.

Talat Yazıcı
Cumhuriyet Cad. Dağ Apt. No.34. D.1
Elmadağ-Şişli/İstanbul

Bu tercümenin yukarıdaki adreste bulunan noterimiz yeminli tercümanı Talat Yazıcı tarafından İngilizce'den Türkçe'ye tercüme edildiğini onaylıyorum.



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

VALIDATION-FOR FDA USE ONLY
VALIDATED BY FDA-26-NOV-2014
DISTRICT: New Jersey
PRINTED BY FDA-04-DEC-2014

PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION AND TYPES OF HCT / PS										14. PROPRIETARY NAME(S)					
3. OTHER FDA REGISTRATIONS		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS										11. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS		12. HCT/PS REGULATED AS MEDICAL DEVICES		13. HCT/PS DESCRIBED IN 21 CFR 1271.10	
a. BLOOD FDA 2630 NO.		Types of HCT / PS															
b. DEVICES FDA 2661 NO. FEI: 0002249062		Establishment Functions															
c. DRUG FDA 2656 NO.		Recover	Screen	Test	Package	Process	Store	Label	Distribute								
		a. Bone	X	X	X	X	X	X	X	X	X	X	X	X	X	X	*** See full text on next page
		b. Cartilage	X	X	X	X	X	X	X	X	X	X	X	X	X	X	*** See full text on next page
		c. Cornea															
		d. Dura Mater															
		e. Embryo															
		f. Fascia	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
		g. Heart Valve															
		h. Ligament	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
		i. Oocyte															
		j. Pericardium	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
		k. Peripheral Blood Stem															
		l. Sclera															
		m. Sperm															
		n. Skin	X	X	X	X	X	X	X	X	X	X	X	X	X	X	*** See full text on next page
		o. Somatic Cell Therapy Products															
		p. Tendon	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
		q. Umbilical Cord Blood															
		r. Vascular Graft															
		s. Amniotic Membrane	X	X	X	X	X	X	X	X	X	X	X	X	X	X	*** See full text on next page
		t.															
		u.															
		v.															



No 16927

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, county, and post office code)
Musculoskeletal Transplant Foundation
Edison Corporate Center
125 May St. Suite 300
Edison, New Jersey 08837

5. ENTER CORRECTIONS TO ITEM 4

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, county, and post office code)
Musculoskeletal Transplant Foundation
Attn: Joel Osborne
Edison Corporate Center
125 May St. Suite 300
Edison, New Jersey 08837

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

9. REPORTING OFFICIAL'S SIGNATURE
a. TYPED NAME Joel C. Osborne
b. E-MAIL ra_licenses@mf.fda.gov
c. TITLE Vice President, RA
d. DATE 25-NOV-2014

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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)

ADDITIONAL INFORMATION:

Proprietary Names:

A. Bone: ENHANCE, DBX Mix, DBX Paste, DBX Putty, Conform Sheet, Luminary CC-ALIP, Luminary T-PLIF, Luminary PLIF, ARCHODL, VarteFill, Conform Flex, ENACT

N. Skin: FlexHD Structural Plus, FlexHD Pliable Perforated, FlexHD Structural, AlloPatch Pliable

Proprietary Name(s):

- a. Bone
 - Conform Putty, Conform Cube, Trinity Evolution, Trinity ELITE, DBX, DBX Strip, DBX Inject, AFT, Allofix, Dental DBX
- n. Skin
 - DermiMatrix, FlexHD, FlexHD Diamond, Allopatch HD, BellaDerm, PerioDerm, FlexHD Pliable
- Amniotic Membrane
 - AmnioClear, AmnioBand, Guardlan, VersaShield, Revitalon, AmnioBand

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