

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: 1000113913

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:16-NOV-2017
DISTRICT: Florida
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)

UMTB Biomedical, Inc.

1951 N.W. 7th Avenue
Suite 200
Miami, Florida 33136

- a. PHONE 786-605-1533 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)

UMTB Biomedical, Inc.
Attn: Juan Rojas
1951 N.W. 7th Avenue
Suite 200
Miami, Florida 33136

- a. PHONE 786-605-1533 EXT

7. ENTER CORRECTIONS TO ITEM 6

b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE



a. TYPED NAME Juan Rojas

b. E-MAIL jrojas@vivex.com

c. TITLE Vice President, Global Quality Systems

d. DATE 15-NOV-2017

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions									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)
	Recover	Screen	Test	Package	Process	Store	Label	Distribute					
a. Bone				X	X	X	X	X	X				*** See full text on next page
b. Cartilage				X	X	X	X	X	X				
c. Cornea													
d. Dura Mater				X	X	X	X	X	X				
e. Embryo	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
f. Fascia				X	X	X	X	X	X				
g. Heart Valve													
h. Ligament				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				
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	X	X				
o. Somatic Cell Therapy Products	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic			X	X	X	X	X	X				*** See full text on next page
p. Tendon				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													
s. Amniotic Membrane				X	X	X	X	X	X				Cygnus
t. Amniotic Fluid				X	X	X	X	X	X				Allogen
u.													
v.													

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ADDITIONAL INFORMATION:

N/A

Proprietary Name(s):

- a. Bone DBM100, DBM Plus, Via Graft, FenFlex, Metis
Macro, Metis Micro, Vega Graft, Jupiter
- o. Somatic Cell Via Graft, Via Form, Via Graft M, Via Form M
Therapy Products