

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:02-DEC-2016
 DISTRICT: Florida
 PRINTED BY FDA:15-DEC-2016

See Instructions for OMB Statement. FORM APPROVED: OMB No. 0910-0543. Expiration Date: 3/31/2017

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

5. ENTER CORRECTIONS TO ITEM 4
 a. PHONE 786-605-1533 EXT
 b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____)
 c. TESTING FOR MICRO-ORGANISMS ONLY

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)
 UMTB Biomedical, Inc. / Vivex Biomedical Inc.
 Attn: Juan Rojas
 Attention Juan Rojas
 1951 NW 7th Ave
 Suite 200
 Miami, Florida 33136

7. ENTER CORRECTIONS TO ITEM 6
 a. PHONE 786-605-1533 EXT
 b. PHONE

8. U.S. AGENT

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 01-DEC-2016

FORM FDA - 3356 (5/14)

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS

Types of HCT / Ps	Establishment Functions					11. HCT/PS DESCRIBED IN CFR 1271.10-21	12. HCT/PS REGULATED AS MEDICAL DEVICES	13. HCT/PS REGULATED AS BIOLOGICAL OR CELLULAR DRUGS	14. PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process				
a. Bone				X	X	X	X	X	X
b. Cartilage				X	X	X	X	X	X
c. Cornea									
d. Dura Mater				X	X	X	X	X	X
e. Embryo									
f. Fascia				X	X	X	X	X	X
g. Heart Valve									
h. Ligament				X	X	X	X	X	X
i. Oocyte									
j. Pericardium				X	X	X	X	X	X
k. Peripheral Blood Stem									
l. Sclera									
m. Semen									
n. Skin				X	X	X	X	X	X
o. Somatic Cell Therapy Products				X	X	X	X	X	X
p. Tendon				X	X	X	X	X	X
q. Umbilical Cord Blood									
r. Vascular Graft									
s. Amniotic Membrane				X	X	X	X	X	Cygnus
t. Amniotic Fluid				X	X	X	X	X	Allotgen
u.									
v.									

*** See full text on next page.

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2

ADDITIONAL INFORMATION:

Proprietary Name(s):

a. Bone DBM100, DBM Plus, Via Graft, FenFlex, Metis
Macro, Metis Micro, Vega Graft, JUPITER