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: 3009510454

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:18-JAN-2018
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 Donor Services Foundation-Jacksonville

3901 University Boulevard, Suite 119
Jacksonville, Florida 32216

a. PHONE 786-605-1533 EXT
b. ☒ SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 1000113913
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 Donor Services Foundation
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 18-JAN-2018

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			
b. Cartilage	X					X			X			
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X					X			X			
g. Heart Valve	X					X			X			
h. Ligament	X					X			X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X					X			X			
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X					X			X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☒ Allogeneic	X					X			X			
p. Tendon	X					X			X			
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X					X			X			
s.												
t.												
u.												
v.												

FORM FDA - 3356 (7/17)