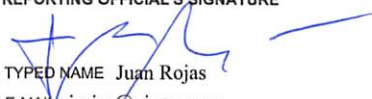


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> (See reverse side for instructions)		<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3012046649	<b>2. REASON FOR SUBMISSION</b> a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:16-NOV-2017 DISTRICT: Florida PRINTED BY FDA:27-JAN-2018																																																																																																																																																																																																																																																	
<b>PART I - ESTABLISHMENT INFORMATION</b>		<b>PART II - PRODUCT INFORMATION</b>							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)																																																																																																																																																																																																																																											
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		<b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> </tr> </thead> <tbody> <tr> <td>a. Bone</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>b. Cartilage</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> </tr> <tr> <td>c. 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<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) UMTB Donor Services Foundation  1951 NW 7th Avenue Suite 200 Miami, Florida 33136  a. PHONE 786-605-1533 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		<b>5. ENTER CORRECTIONS TO ITEM 4</b>																																																																																																																																																																																																																																																			
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) UMTB Donor Services Foundation Attn: Juan Rojas 1951 NW 7th Avenue Suite 200 Miami, Florida 33136  a. PHONE 786-605-1533 EXT _____		<b>7. ENTER CORRECTIONS TO ITEM 6</b>																																																																																																																																																																																																																																																			
<b>8. U.S. AGENT</b>  a. E-MAIL _____		<b>9. REPORTING OFFICIAL'S SIGNATURE</b>   a. TYPED NAME Juan Rojas b. E-MAIL jrojas@vivex.com c. TITLE Vice President, Global Quality Systems d. DATE 15-NOV-2017																																																																																																																																																																																																																																																			

1. REGISTRATION NUMBER  
(FDA Establishment Identifier)

FEI: 3012046649

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/TPs)

(See reverse side for instructions)

ADDITIONAL INFORMATION:

N/A

Proprietary Name(s):