## 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 **DESCRIBED IN 21 CFR 1271.10** 

FEI: 1000113913

Other FDA Registrations:

Blood: Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024 Last Registration Receipt Date: 12/20/2023 Summary Report Print Date: 01/05/2024

Legal Name and Location:

Vivex Biologics, Inc. 2430 NW 116th Street

Ext.:

Miami, Florida 33167

USA

Phone: 786-425-3634

Reporting Official:

Craig Sincaglia, VP of Quality Systems and Regulatory Aff

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Phone: 786-425-3634 Ext. csincaglia@vivex.com

Satellite Recovery Establishment:

No

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only: No

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

		Establishment Functions										
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane					Х	Х	Х	Х	Х			***See full text on next page.
Blood Vessel												
Bone					Х	Х	Х	Х	Х			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage					Х	Х	Х	Х	Х			BioCartilage, VIA Disc NP
Cornea												
Dura Mater												
Embryo												
Fascia					Х	х	Х	Х	Х			
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament					Х	Х	Х	Х	Х			
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium					Х	Х	Х	Х	Х			
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin					Х	Х	Х	Х	Х			***See full text on next page.
Tendon					Х	Х	Х	Х	Х			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Informatio	n: N/A	
Proprietary Name(s):	Amniotic Membrane	Amnii-X, Amnio Maxx, Amniostatis, Amniostratis UC, Amniovo, Arthrex Amnion Matrix, Avant Amnion Patch, Cryo Cord, CYGNUS Cryopreserved Max, CYGNUS Dual, CYGNUS Matrix, CYGNUS Max, CYGNUS Max XL, CYGNUS Solo, FuseChoice Max, FuseChoice Plus, GEO Matrix, GEO UmbiliCORD-C, Maxx Ultra Cord, MIAMNION Dual, MIAMNION Matrix, MIAMNION Single, Pro3-C, Pro3-P, Provenda, Provenda Max, Provenda Solo, Restorigin Amnion Patch, Restorigin SX, Restorigin Dual, Texagen, VIA Matrix, VIAGENEX Cryopreserved Max, VIAGENEX Matrix, VIAGENEX Max
	Bone	Allocyte Plus, Arthrocell, Arthrocell Plus, Avant DBM Cube, Avant DBM Strip, CelLogix, CelLogix Formable, CelLogix Moldable, CuriGraft DBM, CuriGraft Viable Allogenic Bone Matrix, DBLogix, Endurifuse, FENFLEX, FuseTrilogy, Inteligraft, Magnus, Medicus Viable Bone, Nevos Flex, Nevos Sponge, NoRad, Orios, Orios Moldable, Orios Moldable Plus, Orios XT, OsteoSource, OsteoSource DBM, OsteoVive, RS Form Moldable, V92 Cellular Bone Matrix, V92 FiberCell, V92 FC+ Vega Graft, VIA DBM Sponge, VIA DBM Strip, VIA Fill, VIA Form M, VIA FORM+, VIA Graft, VIA Graft M, VIA Thrive
	Skin	Derm-Maxx, FuseChoice Derm, FuseChoice Derm Max, Paraderm, VIA DERMIS

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