

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: 2022 Last Registration Receipt Date: 12/10/2021 Summary Report Print Date: 12/15/2021
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Legal Name and Location: VIVEX Biologics, Inc. 2430 NW 116th Street Miami, Florida 33167 USA Phone: 786-605-1533 Ext.:	Reporting Official: Juan P Rojas, Vice President, Quality Systems 2430 NW 116th Street Miami, Florida 33167 USA Phone: 786-605-1533 Ext. jrojas@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)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane					X	X	X	X	X			***See full text on next page.
Blood Vessel												
Bone					X	X	X	X	X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage					X	X	X	X	X			VIA Disc NP
Cornea												
Dura Mater												
Embryo												
Fascia					X	X	X	X	X			
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament					X	X	X	X	X			
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium					X	X	X	X	X			
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin					X	X	X	X	X			***See full text on next page.
Tendon					X	X	X	X	X			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue					X	X	X	X	X			***See full text on next page.

Additional Information: N/A

Proprietary Name(s):	Amniotic Membrane	MIAMNION Single, MIAMNION Dual, MIAMNION Matrix, CYGNUS Solo, FuseChoice, CYGNUS Matrix, FuseChoice Plus, GEO Matrix Amnii-X, Amniovo, Amnio Maxx, AmnioStratis, Pro3-P, Provenda, TEXAGEN, VIAGENEX Matrix
	Bone	VIAFill, CuriGraft, VIA Graft, VIA Graft M, FuseTrilogy, VIA Form M, Fenflex, Vega Graft, ArthroCell, CeLLogix, DBLogix, Indux, Magnus, Nevos, Orios, Paragon V92, Scylla, StaGraft, V92 Fiber, VIA Form+, CuriGraft Viable Allogenic Bone Matrix, V92 FC+, RS Form Moldable, Medicus Viable Bone, Endurifuse, Osteosource, VIA DBM Flex Fenestrated, VIA DBM Sponge, VIA Thrive, VIA Cancellous+
	Skin	FuseDerm, FuseDerm Plus, FuseDerm Max, Derm-Maxx, Paraderm, VIA DERMIS
	Umbilical Cord Tissue	CYGNUS Max, CYGNUS Max XL, CYGNUS Cryopreserved Max, FuseChoice Max, GEO UmbiliCORD, AmnoiStratis UC, Arthrex Amnion Cord, Cryo Cord, Cryo UC, GEO UmbiliCORD-C, Maxx Ultra Cord, Pro3-C, Provenda Max, VIAGENEX Max, VIAGENEX Cryopreserved Max

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