

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: 2025 Last Registration Receipt Date: 11/25/2024 Summary Report Print Date: 12/05/2024
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Legal Name and Location: Vivex Biologics, Inc. 2430 NW 116th Street Miami, Florida 33167 USA Phone: 786-425-3634 Ext.:	Reporting Official: Craig Sincaglia, VP of Quality Systems and Regulatory Aff 2430 NW 116th Street Miami, Florida 33167 USA 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)).
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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			BioCartilage, VIA Disc NP
Cornea												
Dura Mater												
Embryo												
Fascia								X				
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament								X				
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin					X	X	X	X	X			***See full text on next page.
Tendon								X				
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: N/A

Proprietary Name(s):	Amniotic Membrane	Amnii-X, Amnio Maxx, Amniostatis, Amniostratis UC, Amniovo, Arthrex Amnion Matrix, Avant Amnion Patch, CYGNUS Disk, CYGNUS Dual, CYGNUS Matrix, CYGNUS Max, CYGNUS Max XL, CYGNUS Solo, FuseChoice Max, FuseChoice Plus, GEO Matrix, 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 Matrix, VIAGENEX Max, VIAGENEX Solo
	Bone	Alloocyte 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+, VIA DBM Sponge, VIA DBM Strip, VIA Fill, VIA Form Pro, VIA Form M, VIA FORM+, VIA Graft, VIA Graft M, VIA Thrive, Viable Matrix Plus
	Skin	Derm-Maxx, FuseChoice Derm, FuseChoice Derm Max, Paraderm, VIA DERMIS, VIA DERMIS XL

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