## 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

Ext.:

FEI: 3009838457

Other FDA Registrations: Blood: Devices:

Drugs:

Reason For Last Submission: Change in Information
Last Annual Registration Year: 2024
Last Registration Receipt Date: 01/03/2024
Summary Report Print Date: 01/05/2024

No

Legal Name and Location:

Stability Biologics, LLC 1077 Central Parkway South

Suite 500

San Antonio, Texas 78232

USA

Phone: 210-233-6733

Reporting Official:

Terry Hill, Chief Operating Officer /Tissue Bank Dir

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Suite 500

San Antonio, Texas 78232

USA

Phone: 210-424-7308 Ext. thill@stabilitybio.com

Satellite Recovery Establishment:

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	Х			***See full text on next page.
Blood Vessel												
Bone			Х		Х	Х	Х	Х	Х			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin							Х		Х			InteguPly
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	DeltaStrand, AlphaFuse, Charlie 1, EchoSponge, LimaCore added 10/7/2020 AmnioCore Burn added 10/30/2020 AmnioCore OP added 7/29/2021 AmnioCore Flow Lyophilized & ZipGraft removed 8/30/2021 AmnioCore Surgical added 10/25/2021 Amnio Tri-Core added 3/4/2022 Amnio Quad-Core added 3/4/2022 Amnio Tri-Core Surgical added 12/21/22 Amnio Quad-Core Surgical added 12/21/22 Amnio Quad-Core Surgical added 12/21/22 AmnioCore Pro added 3/29/23
	Amnio Quad-Core Surgical added 12/21/22
	AmnioCore Pro+ added 3/29/23
	Dermacyte added 6/29/23
	AmnioAMP-MP added 6/29/23

NeoStim AmnioCore AC added 10/26/23 AmnioCore SL added 12/4/23 NeoStim removed 1/2/24

## Proprietary Name(s)

(s):	Amniotic Membrane	AmnioCore, AmnioCore Surgical, AmnioCore Particulate, AmnioCore Burn, AmnioCore OP, Amnio Tri-Core, Amnio Quad-Core, LimaCore, Amnio Tri-Core Surgical, Amnio Quad-Core Surgical, AmnioCore AC, AmnioCore Pro, AmnioCore Pro, AmnioCore SL, Dermacyte, AmnioAMP-MP
	Bone	Physio Moldable, Physio Blend, H100 DBM Putty, H100 DBM Crush-Mix, BioSponge, Cortical Fibers, ZVPro, ZVMax, Charlie 1, AlphaFuse, DeltaStrand, EchoSponge

FEI: 3009838457 Legal Name: Stability Biologics, LLC