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.: 1680

FEI: 3004142400

Other FDA Registrations: Blood:

Devices:FEI: 3004142400

Drugs:

Fatablish mant Freezie

Reason For Last Submission: Change in Information

Last Annual Registration Year: 2023 Last Registration Receipt Date: 04/10/2023 Summary Report Print Date: 04/18/2023

Legal Name and Location:

Globus Medical, Inc.
Valley Forge Business Center
2560 General Armistead Avenue

Audubon, Pennsylvania 19403

USA

Phone: 610-930-1800

Reporting Official:

Daniel S Paul, Senior VP - Corporate Quality & IT

Valley Forge Business Center 2560 General Armistead Avenue Audubon, Pennsylvania 19403

USA

Phone: 610-930-1800 Ext. 1680 dspaul@globusmedical.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			ViaShield
Blood Vessel												
Bone							Х	Х	Χ			***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												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

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Proprietary Name(s):	Bone	COALITION AGX Allograft Spacer, CROSSWAY, DBM InstaFill Cartridge, FORGE, INDEPENDENCE MIS AGX Allograft Spacer, Ossifuse HSA, XEMPLIFI, ViaSorb, ViaCell, Trifecta

FEI: 3004142400 Legal Name: Globus Medical, Inc.

Additional Information:

No additional information provided.