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: 3004142400

Other FDA Registrations: Blood:

Devices:FEI: 3004142400

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2019
Last Registration Receipt Date: 12/13/2018
Summary Report Print Date: 12/19/2018

Legal Name and Location:

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

Audubon, Pennsylvania 19403

USA

Phone: 610-930-1800 **Ext.:** 1680

Reporting Official:

Daniel S Paul, Senior VP - Corporate Quality & IT

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

Phone: 610-930-1800 Ext. 1680 dspaul@globusmedical.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)).

No

HCT/P(s)	Donor Type(s)		Establishment Functions									
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane							Х	Х	X			ViaShield
Blood Vessel												
Bone							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												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: No additional information provided.

Proprietary Name(s): Bone MAINTAIN, XEMPLIFI, FORGE, COALITION AGX Allograft Spacer, ViaSorb, ViaCell

FEI: 3004142400 FDA information collection OMB Control number: 0910-0543, expiration date: 6/30/2020 Legal Name: