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: 3016678141

Other FDA Registrations: Blood:

Devices: Drugs: Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2023 Last Registration Receipt Date: 12/06/2022 Summary Report Print Date: 12/15/2022

Legal Name and Location:

Origin Biologics, LLC 6635 S. Eastern Avenue

Suite 100

Las Vegas, Nevada 89119

USA

Phone: 702-790-7015

Reporting Official:

Melisa Gilchrist, Quality Manager

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Phone: 702-790-7025 Ext. 7019 melisa.gilchrist@originbio.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	х	Х	Х			
Blood Vessel												
Bone			Х		Х	х	Х	Х	Х			See attached list
Cardiac Tissue - non-valved												
Cartilage			Х		Х	Х	Х	X	Х			
Cornea												
Dura Mater												
Embryo												
Fascia			Х		Х	х	Х	Х	Х			
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament			Х		Х	Х	Х	Х	Х			
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin			Х		Х	Х	Х	Х	Х			
Tendon			Х		Х	Х	Х	Х	Х			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue			Х		Х	Х	Х	Х	Х			

Fatablish mant Freezie

Additional Information:

List of Products:

AcuGraft H Spacer, Allocell AF, Allocyte Advanced Cellular Matrix, Cortical Allograft, Demin Cancellous Strips, Cancellous Chips, Demineralized Granules, Cancellous Flex Demin Strip, Fiber Complete, FibreX, InFill CBM, OsseoGEN, Ossify Cortical Fiber, OsteoVive Plus, Restrux Viable Cell Matrix, Magnus Viable Cellular Allograft, SeptumStrip, Septum Segment, System 3 Bone Matrix, Unifyber, VitaeOS, Zavatrix, Avante Fiber Complete, Unifyber, ProGraft Fiber, Bulk Water Rinse, Osteovance FiberFlow, Osteovance FiberFlow, Osteovance Matrix Strip, Osteovance Matrix, Osteovance Matrix Plus, Osteovance Structure C, Osteovance Active, Osteovance Flow, Osteovance Flow Plus, Origin Brand Fiber, Origin Brand Fiber, Origin Brand Putty, Origin Brand Putty, Origin Brand Putty, Origin Brand Putty Plus, Alphagraft DBM Fiber, OB Costal Cartilage Allograft, Cervical Spacer, Cortical Cancellous Cervical Spacer, SI Dowel, DBM Fiber Nest, Tetrous DBM Fiber

Proprietary Name(s):

FEI: 3016678141

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