

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: 1000100754

Other FDA Registrations:

Blood:

Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2022
Last Registration Receipt Date: 12/27/2021
Summary Report Print Date: 01/05/2022

Legal Name and Location:

Aziyo Biologics, Inc.
880 Harbour Way South
Suite 100

Richmond, California 94804
USA

Phone: 855-416-0596

Ext.:

Reporting Official:

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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)	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	X			***See full text on next page.
Blood Vessel												
Bone			X		X	X	X	X	X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage			X		X	X	X	X	X			TranZgraft
Cornea												
Dura Mater												
Embryo												
Fascia			X		X	X	X	X	X			TranZgraft
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament			X		X	X	X	X	X			TranZgraft
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium										01-DEC-19		
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin			X		X	X	X	X	X			***See full text on next page.
Tendon			X		X	X	X	X	X			TranZgraft
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue										28-MAY-21		

Additional Information: No additional information provided.

Proprietary Name(s): Amniotic Membrane	AlloAid Amniotic Allograft Cover, AlloAid StimDisk, AlloGuide GF, AltiPly, AltiPly Duo, AltiPly Lite, AmnioRepair, Xcell Amnio Matrix, Xcellerate, XcellerEYES
Bone	ACTIVI, AcuPac, AcuPac Deformity, AlloAid BioNail, AlloAid DIP, AlloAid Nail, AlloAid PIP, Allograft Cancellous Bone, AlloOss Plus, BioFuse, BioFuse Pro, FiberCel, Fibri-Cell, Isto Cancellous Chips, JoinTac, OmniArch Anatomic Wedge System, OsteGro, OsteGro F, OsteGro V, OsteoXcell, OsteSpine, SILO, Spectrum C, Spectrum Interbody, Surgalign Cancellous Chips, STRATOFUSE V, Tempest, Tempest VX, TENFUSE, TranZgraft, Trifecta, ViBone, ViBone Moldable, ViMax, X-Graft, X-Wedge System
Skin	AlloAid DM, DermaSpan ACD, DeraSpan R, Derm-Maxx, InteguPly Acellular Dermis, MemoDerm Acellular Dermal Matrix, SimpliDerm, TigoDerm, VivaDerm, XcelleDERM

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