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: 3031984391

Other FDA Registrations:

Blood: Devices: Drugs:

Reason For Last Submission: Initial Registration/Listing

Last Annual Registration Year: 2024 Last Registration Receipt Date: 08/19/2024 Summary Report Print Date: 08/19/2024

Legal Name and Location:

Dorotea, LLC dba Precision Allograft Solutions

12727 Cimarron Path

San Antonio, Texas 78249

USA

Phone: 210-736-2663

Reporting Official:

Evan C Villarreal. Director of QA/RA

12727 Cimarron Path

San Antonio, Texas 78249

Phone: 210-138-2663 Ext. 14 evillarreal@alamobiologics.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)).

	Donor Type(s)		Establishment Functions									
HCT/P(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			
Cardiac Tissue - non-valved												
Cartilage			Х		Х	Х	Х	Х	Х			
Cornea			Х		Х	Х	Х	Х	Х			
Dura Mater												
Embryo												
Fascia			Х		X	Х	Х	X	Х			
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament			Х		Х	X	Х	Х	Х			
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium			Х		х	х	Х	Х	Х			
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera			Х		х	х	Х	Х	х			
Semen												
Skin			Х		х	Х	Х	Х	Х			
Tendon			Х		х	Х	Х	Х	Х			EvoGraft
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue			Х		Х	Х	х	Х	х			

Proprietary Name(s):	Amniotic Membrane	AmnioBioGraft, EvoPatch, OL Patch						

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Additional Information:

No additional information provided.