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: 3009085719

Other FDA Registrations: Blood:

Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024 Last Registration Receipt Date: 12/18/2023 Summary Report Print Date: 01/05/2024

Legal Name and Location:

Dorotea, LLC dba Precision Allograft Solutions

5844 Rocky Point

Miles D Lanning, Vice President, QA/RA

P.O. Box 691433

Reporting Official:

San Antonio, Texas 78269

Phone: 210-738-2663 Ext. 18 mlanning@alamobiologics.com

Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only:

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

No

1271.27(b)).

San Antonio, Texas 78249

USA

Phone: 800-226-9091

	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			AmnioBioGraft
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		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			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			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue			Х		Х	Х	Х	Х	Х			

Additional Information:	No additional information provided.

Proprietary Name(s):

FEI: 3009085719 Legal Name: Dorotea, LLC dba Precision Allograft Solutions