## 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: 3007950337

Reporting Official:

Other FDA Registrations: Blood:

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

Last Annual Registration Year: 2023 Last Registration Receipt Date: 11/21/2022 Summary Report Print Date: 12/01/2022

Legal Name and Location:

San Antonio, Texas 78249

Phone: 800-226-9091

Dorotea, LLC dba BioRepository Service

5844 Rocky Point

USA

Miles D Lanning, Vice President, QA/RA P.O. Box 691433

San Antonio, Texas 78269

USA

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

Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.: 3009085719

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 Date of Date of Proprietary Name(s) Donor Type(s) Package HCT/P(s) Screen Donor Testina Process Store Label Distribute Discontinuance Resumption Χ AmnioBioGraft Amniotic Membrane Χ Blood Vessel Χ Bone Cardiac Tissue - non-valved Cartilage Χ Х Cornea Х Dura Mater Χ Embryo Anonymous, Directed, SIP Χ Fascia Heart Valve Χ Х **HPC Apheresis** Autologous, Family Related HPC Cord Blood Autologous, Family Related Χ Χ Ligament Nerve Tissue Oocyte Anonymous, Directed, SIP Χ Ovarian Tissue Pancreatic Islet Cells - autologous Parathyroid Pericardium Χ Peripheral Blood Mononuclear Cells Peritoneal Membrane Χ Sclera Semen Anonymous, Directed, SIP Х Skin Χ Tendon Χ Testicular Tissue Tooth Pulp Χ **Umbilical Cord Tissue** 

Additional Information:	No additional information provided

Proprietary Name(s):

FEI: 3007950337 Legal Name: Dorotea, LLC dba BioRepository Service