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: 3004430789

Other FDA Registrations: Blood: FEI: 3004430789

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

Last Annual Registration Year: 2024 Last Registration Receipt Date: 11/27/2023 Summary Report Print Date: 12/01/2023

Legal Name and Location:

Southwest Transplant Alliance

7618 Boeing Drive Suite B

El Paso, Texas 79925

USA

Phone: 214-522-0255

Reporting Official:

Jaskiran Kaur, Director of Quality Systems

8190 Manderville Ln Dallas, Texas 75231

USA

Phone: 630-362-5762 Ext.

jkaur@organ.org

Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.: 3003268751

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												
Blood Vessel		Х										
Bone		х										
Cardiac Tissue - non-valved		Х										
Cartilage		Х										
Cornea		Х										
Dura Mater												
Embryo												
Fascia		Х										
Heart Valve		X										
HPC Apheresis												
HPC Cord Blood												
Ligament		X										
Nerve Tissue		X										
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium		Х										
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		Х										
Semen												
Skin		х										
Tendon		х										
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	Donor testing and screening is not performed at El Paso facility. These functions are performed at the Dallas Corporate location. This was listed as an observation in the August 2023 FDA Inspection of the FDA facility.

Proprietary Name(s):

FEI: 3004430789 Legal Name: Southwest Transplant Alliance