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: 3014769200

Other FDA Registrations: Blood:

Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025 Last Registration Receipt Date: 11/18/2024 Summary Report Print Date: 12/05/2024

Legal Name and Location:

United Tissue Resources, LLC 8105 Exchange Drive

Austin, Texas 78754

Phone: 512-206-1128

USA

Reporting Official: Wendy Bailey, Director, Quality Assurance 4300 N. Lamar Blvd.

Austin, Texas 78756

Phone: 512-206-1134 Ext.

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

Additional Information:	Per email October 12, 2018 ORA issued a new FEI number 3014769200.	The old FEI number was 0001671794.

Proprietary Name(s):

FEI: 3014769200 Legal Name: United Tissue Resources, LLC