

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,  TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS  DESCRIBED IN 21 CFR 1271.10</b>	<b>FEI:</b> 3001238005	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> <b>Drugs:</b>	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2023 Last Registration Receipt Date: 12/02/2022 Summary Report Print Date: 12/15/2022
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<b>Legal Name and Location:</b>  Transplant Services Center UT Southwestern Medical Center 2330 Inwood Road, Suite EB 2.400  Dallas, Texas 75235 USA  Phone: 214-648-2609 <b>Ext.:</b>	<b>Reporting Official:</b> Richard Jordan, Associate Director 5323 Harry Hines, MC 9074 Dallas, Texas 75390-9074 USA Phone: 214-645-0995 Ext. richard.jordan@utsouthwestern.edu	<b>Satellite Recovery Establishment:</b> No <b>Parent Manufacturing Establishment FEI No.:</b> <b>Testing For Micro-Organisms Only:</b> 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)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane								X		X		Prokera
Blood Vessel		X	X									
Bone		X	X					X		X		***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage		X	X		X	X	X	X	X			
Cornea		X	X		X	X	X	X	X			
Dura Mater												
Embryo												
Fascia		X	X		X	X	X	X	X			
Heart Valve		X	X									
HPC Apheresis												
HPC Cord Blood												
Ligament		X	X					X		X		
Nerve Tissue								X		X		Avance
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid					X	X	X	X	X			Autologous Parathyroid
Pericardium		X	X					X		X		
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		X	X		X	X	X	X	X			
Semen												
Skin		X	X		X	X	X	X	X			
Tendon		X	X					X		X		
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

**Additional Information:** None

<b>Proprietary Name(s):</b> Bone	Including Autologous Skull Flap
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FEI: 3001238005

Legal Name: Transplant Services Center UT Southwestern Medical Center