

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	FEI: 3008927553	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Change in Information Last Annual Registration Year: 2020 Last Registration Receipt Date: 08/21/2020 Summary Report Print Date: 09/18/2020
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Legal Name and Location: Pinnacle Transplant Technologies, LLC 1125 W. Pinnacle Peak Rd Bldg 1 and 2 Phoenix, Arizona 85027 USA Phone: 623-277-5400 Ext.: 405	Reporting Official: Danielle Rose T Cox, Regulatory Affairs Specialist 1125 W. Pinnacle Peak Rd Bldg 1 Phoenix, Arizona 85027 USA Phone: 623-277-5400 Ext. 441 dcox@pinnacletransplant.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)).
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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	X	X	X	X	X			***See full text on next page.
Blood Vessel												
Bone			X	X	X	X	X	X	X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage			X	X	X	X	X	X	X			
Cornea												
Dura Mater												
Embryo												
Fascia			X	X	X	X	X	X	X			
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament			X	X	X	X	X	X	X			
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin			X	X	X	X	X	X	X			
Tendon			X	X	X	X	X	X	X			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: Amniotic Membrane - (Continuation) SuiGen Membrane, SuiGen Hydromembrane, Stratogen Plus Membrane, Stratogen Membrane, PalinGen XPlus Membrane

Proprietary Name(s):	Amniotic Membrane	Palingen Membrane, Palingen Hydromembrane, Palingen XPlus Hydromembrane, Kardia Membrane, SX Barrier, ASGBarrier
	Bone	iFuse Bone, Stratofuse, Apex DBM Putty, Apex DBM Crunch, Apex DBM Fiber, Apex FP, Apex FP Plus, Ossif-isem (tm)

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