

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: FEI: 3008927553 Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2019 Last Registration Receipt Date: 12/21/2018 Summary Report Print Date: 01/28/2019
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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 Apex DBM Putty, Apex DBM Crunch, Apex DBM Fiber, Apex FP, Apex FP Plus, Ossif-istem (tm)