

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: Annual Registration/Listing Last Annual Registration Year: 2024 Last Registration Receipt Date: 12/13/2023 Summary Report Print Date: 12/15/2023
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Legal Name and Location: Pinnacle Transplant Technologies, LLC 1125 W. Pinnacle Peak Rd Bldg 1 & Bldg 2 Phoenix, Arizona 85027 USA Phone: 623-277-5400 Ext.:	Reporting Official: Casey M Ming, Director of Regulatory Affairs 1125 W. Pinnacle Peak Rd Bldg 1 & Bldg 2 Phoenix, Arizona 85027 USA Phone: 623-277-5400 Ext. 434 cming@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			See additional listing
Blood Vessel												
Bone			X		X	X	X	X	X			See additional listing
Cardiac Tissue - non-valved												
Cartilage			X		X	X	X	X	X			
Cornea												
Dura Mater												
Embryo												
Fascia			X		X	X	X	X	X			
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament			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			
Tendon			X		X	X	X	X	X			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:

Bone: Legacy V, SIBI Cage, iFuse Bone, Infinity DBM, DBMPure Macro, DBMForm, Apex DBM, STRATOFUSE, Allos, Nevos DBM, Re-Live, APEX DBM, Allofill Donors, Evoke, FusePure, Influencer, XCITE, Fibrant, Influx, Invictus, ORIO TriOsteo, REFuZE DBM, Ossify, Unio SI, CornerLoc, TheraFuze DBF, TeleGraft, DBM, CerLoc, SiJoin, VerteLoc, Multitude, ZVPro

Amniotic Membrane: Axolotl Graft, Axolotl DualGraft, Luminel, ASGBarrier, ASGBarrier-Wet, STRATOGEN, Cocoon, PalinGen, GrowFX, Impax, Orion, SuiGen, SXBarrier, Zenith

Proprietary Name(s):

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