

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> 3008927553	<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: 2025 Last Registration Receipt Date: 12/04/2024 Summary Report Print Date: 12/05/2024
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<b>Legal Name and Location:</b>  Pinnacle Transplant Technologies, LLC 1125 W. Pinnacle Peak Rd Bldg 1,2,4  Phoenix, Arizona 85027 USA  Phone: 623-277-5400 <b>Ext.:</b>	<b>Reporting Official:</b> Casey M Ming, Director of Regulatory Affairs 1125 W. Pinnacle Peak Rd Bldg 1 Phoenix, Arizona 85027 USA Phone: 623-277-5400 Ext. 434 cming@pinnacletransplant.com	<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	X	X	X	X			***See full text on next page.
Blood Vessel												
Bone			X		X	X	X	X	X			***See full text on next page.
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, Renastere, Renati, Amnio Burgeon Membrane, Amnio Burgeon Hydromembrane, Amnio Burgeon Xplus Membrane, Amnio Burgeon Xplus Hydromembrane, Amnio Burgeon Dual-layer Membrane, Dual Layer Amnio Burgeon X-Membrane, Abiomend Membrane, Abiomend Hydromembrane, Abiomend XPlus Membrane, Abiomend Xplus Hydromembrane

<b>Proprietary Name(s):</b> Amniotic Membrane	Axolotl Graft, Axolotl DualGraft, Luminel, ASGBarrier, ASGBarrier-Wet, STRATOGEN, Cocoon, PalinGen, GrowFX, Impax, Orion, SuiGen, SXBarrier, Zenith, Renastere, Renati, Amnio Burgeon Membrane, Amnio Burgeon Hydromembrane, Amnio Burgeon Xplus Membrane, Amnio Burgeon Xplus Hydromembrane, Amnio Burgeon Duallayer Membrane, Dual Layer Amnio Burgeon X-Membrane, Abiomend Membrane, Abiomend Hydromembrane, Abiomend XPlus Membrane, Abiomend Xplus Hydromembrane
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

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