

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: 2022 Last Registration Receipt Date: 11/30/2021 Summary Report Print Date: 12/01/2021
--	------------------------	--	---

<b>Legal Name and Location:</b>  Pinnacle Transplant Technologies, LLC 1125 W. Pinnacle Peak Rd Bldg 1  Phoenix, Arizona 85027 USA  Phone: 623-277-5400 <b>Ext.:</b>	<b>Reporting Official:</b>  Candice Chen, Manufacturing Engineer 1125 W. Pinnacle Peak Rd Bldg 1 Phoenix, Arizona 85027 USA Phone: 623-277-5400 Ext. 434 cchen@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)).
---	---	--

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	X			
Tendon			X		X	X	X	X	X			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

**Additional Information:** No additional information provided.

<b>Proprietary Name(s):</b> Amniotic Membrane	PalinGen Membrane, PalinGen Hydromembrane, PalinGen XPlus Membrane, PalinGen XPlus Hydromembrane, PalinGen Dual Layer Membrane, Dual Layer PalinGen X-Membrane, SXBarrier, ASGBarrier, SuiGen Membrane, SuiGen Hydromembrane, SuiGen XPlus Membrane, SuiGen XPlus Hydromembrane, STRATOGEN Membrane, STRATOGEN Plus Membrane, Zenith Amniotic Membrane, Axolotl Single Layer Graft, Axolotl Dual Layer Graft
Bone	APEX DBM Putty, APEX DBM Crunch, APEX DBM Fiber, APEX DBM Fiber Putty, APEX DBM Fiber Putty Plus, APEX DBM Cancellous Chips, APEX DBM Sponge Block, APEX DBM Sponge Strip, APEX DBM Fiber Boat, iFuse Bone, STRATOFUSE, Re-Live Triangular Multi-Point Allograft, CornerLoc SI Cortical Graft, FusePure, NMP, Infinity, Legacy V-LC4SM, PURfuze, PUR Basic, Allos CC7, Allos CC7 XL, Allos Granules, Allos MC5, Allos MC5 XL, Nevos, TeleGraft, DBMForm, DBMPure, ORIO TriOsteo Trapezoidal, Ossify 100% DBM Putty, TheraFuze DBF Moldable, TheraFuze DBF S, TheraFuze DBF Plus Moldable, TheraFuze DBF Plus S, TheraFuze DBF Wrap, TheraFuze DBF Boat, TheraFuze DBF Fiber Bag, TheraFuze DBF Anchor, TheraFuze DBF Fiber Bullets, SIBI Cage, ZVPro, ZVPro Crush-Mix, Multitude, Multitude Crush-Mix

FEI: 3008927553

Legal Name:

Pinnacle Transplant Technologies, LLC