

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: 3006228878	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2022 Last Registration Receipt Date: 11/21/2021 Summary Report Print Date: 12/01/2021
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Legal Name and Location: Empire Medical 32395 Clinton Keith Rd Ste. A202 Wildomar, California 92595 USA Phone: 951-383-9291 Ext.:	Reporting Official: Emmanuel Sanchez, Tissue Bank Director 39252 Winchester Rd. Ste. 107#154 Murrieta, California 92563 USA Phone: 951-282-9666 Ext. esanchez@empiremed.org	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			***See full text on next page.
Blood Vessel												
Bone							X		X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage							X		X			Biocartilage, Cartiform
Cornea												
Dura Mater												
Embryo												
Fascia							X		X			Fascia Latta
Heart Valve												
HPC Apheresis												
HPC Cord Blood	Autologous, Family Related						X		X			
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin							X		X			Arthroflex
Tendon							X		X			***See full text on next page.
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue							X		X			Centaflex

Additional Information: No additional information provided.

Proprietary Name(s): Amniotic Membrane	ArthroCell and Amnion; Biovance, Biovance 3L, Intertyl
Bone	ArthroCell, Tibia, cancellous bone chips, Stimublast, AlloSync
Tendon	Graftlink, Pre-sutured lateral ankle tendon, Patella, Ant/ Post Tib, Peroneas, Achilles, SemiTen., Gracilis

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Legal Name:

Empire Medical