## 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**

Ext.:

FEI: 3015990348

Other FDA Registrations: Blood:

Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2023 Last Registration Receipt Date: 08/24/2023 Summary Report Print Date: 08/29/2023

Legal Name and Location:

Empire Medical (Redlands) 310 Alabama St. Suite I

Redlands, California 92373

Phone: 951-414-9017

USA

Reporting Official: Amanda Salgado, Tissue Director 39252 Winchester Rd. Ste. 107#154 Murrieta, California 92563

Phone: 951-326-9393 Ext. asalgado@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)).

	Donor Type(s)		Establishment Functions									
HCT/P(s)		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane							Х		х			***See full text on next page.
Blood Vessel												
Bone							Х		Х			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage							Х		X			***See full text on next page.
Cornea												
Dura Mater												
Embryo												
Fascia							Х		X			Fascia Latta
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament							Х		х			***See full text on next page.
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin							Х		Х			Arthroflex
Tendon							Х		Х			***See full text on next page.
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue							Х		Х			Centaflex

Additional Information: No additional information provided.						
Proprietary Name(s):	Amniotic Membrane	ArthroCell and Amnion; Biovance, Biovance 3L, Intertyl				
	Bone	ArthroCell, Femoral, Tibia, Cancellous, Bone Chips, Stimublast				
	Cartilage	BioCartilage, Cartiform, Allosync gel, putty, paste, Allosync Demineralized Cubes Strips, Chips, Fibers, AlloSync Pure				
	Ligament	Patellar Ligament, Pre-shaped Patellar Ligament				
	Tendon	GraftLink, Pre-sutured Lateral ankle, Patella, Anterior/Posterior Tibialis, Peroneus, Achilles, Semi-T, Gracilis				