## 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: 3011724981

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 (ANAHEIM) 1200 North Jefferson St. unit F Gel Luague, Tissue Director 39252 Winchester Rd. Ste. 107#154 Murrieta, California 92563 USA Phone: 562-841-2584 Ext.

gluague@empiremed.org

Reporting Official:

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)).

Anaheim, California 92807

USA

Phone: 951-414-9017

Ext.:

		Establishment Functions										
HCT/P(s)	Donor Type(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		X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage							Х		Х			Biocartilage; Cartiform;
Cornea												
Dura Mater												
Embryo												
Fascia							Х		Х			Fascia Latta
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
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 ,Tibia, cancellous bone chips, Stimublast, AlloSync				
	Tendon	Graftlink,Pre-sutured lateral ankle, Patella, Ant-Tib, Post-Tib, Peroneus, Achilles, Semi-T, Gracilis				

FEI: 3011724981 Legal Name: Empire Medical (ANAHEIM)