

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> 3019473718	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> <b>Drugs:</b>	Reason For Last Submission: Initial Registration/Listing Last Annual Registration Year: 2021 Last Registration Receipt Date: 06/23/2021 Summary Report Print Date: 06/23/2021
--	------------------------	--	--

<b>Legal Name and Location:</b>  Empire Medical (ONTARIO) 4345 E. Lowell Street, Ste. B   Ontario, California 91761 USA  Phone: 951-383-9291 <b>Ext.:</b>	<b>Reporting Official:</b> Nicole Johansen, Ontario Office Manager 39252 Winchester Rd Ste. 107-154 Murrieta, California 92563 USA Phone: 949-573-0685 Ext. njohansen@empiremed.org	<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			Arthrocell and Amnion
Blood Vessel												
Bone							X		X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia							X		X			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							X		X			Arthroflex
Tendon							X		X			***See full text on next page.
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

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

Proprietary Name(s):	Bone	ArthroCell, Tibia, Cancellous Bone Chips; Stimblast; AlloSync
	Tendon	Graftlink, Pre-sutured lateral ankle, Patella, Anterior and Posterior Tibialis, Peroneus, Achilles, Semi-T, Gracilis

FEI: 3019473718

Legal Name:

Empire Medical (ONTARIO)