

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: 2020
 Last Registration Receipt Date: 01/09/2020
 Summary Report Print Date: 01/30/2020

Legal Name and Location:

SportsTek Medical, Inc. (Temecula)
 27313 Via Industria

Temecula, California 92590
 USA

Phone: 951-296-2108

Ext.:

Reporting Official:

Samuel Dodson, Tissue Bank Director
 27313 Via Industria
 Temecula, California 92590
 USA
 Phone: 951-296-2108 Ext.
 sdodson@sportstekmedical.com

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)).

Establishment Functions

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							X		X			Biocartilage, Cartiform
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, Stimublast, AlloSync
Tendon	Graftlink, Pre-sutured lateral ankle tendon, Patella, Ant/ Post Tib, Peroneas, Achilles, SemiTen., Gracilis

FEI: 3006228878

Legal Name:

SportsTek Medical, Inc. (Temecula)