

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: 3010007795

Other FDA Registrations:
Blood:
Devices:
Drugs:

Reason For Last Submission: Change in Information
Last Annual Registration Year: 2020
Last Registration Receipt Date: 01/22/2020
Summary Report Print Date: 01/31/2020

Legal Name and Location:

SportsTek Medical Inc.(Hawaii)
729 E. Emily Street

Honolulu, Hawaii 96813
USA

Phone: 808-230-1753

Ext.:

Reporting Official:

Emily Nyenhuis, Tissue Director
27313 Via Industria
Temecula, California 92590
USA
Phone: 865-724-4603 Ext.
emilyn@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, Femoral,Tibia, cancellous, bone chips,Stimublast, AlloSync
	Tendon	Graftlink,Pre-sutured lateral ankle, Patella, Ant-Tib, Post-Tib, Peroneus, Achilles, Semi-T,Gracilis

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