

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: 3008865245	Other FDA Registrations: Blood: Devices: FEI: 0300916996 Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2019 Last Registration Receipt Date: 12/03/2018 Summary Report Print Date: 12/19/2018
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Legal Name and Location: NuTech Spine, Inc. 600 Luckie Drive Suite 424 Birmingham, Alabama 35223 USA Phone: 205-533-7709	Reporting Official: Rachel Cromer, Quality Director 600 Luckie Drive Suite 424 Birmingham, Alabama 35223 USA Phone: 205-533-7709 Ext. rcromer@nutechspine.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)).
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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												
Blood Vessel												
Bone							X		X			NuFix, NuFix II, SIFix, DuALIF
Cardiac Tissue - non-valved												
Cartilage							X		X			
Cornea												
Dura Mater												
Embryo												
Fascia							X		X			
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament							X		X			
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium							X		X			
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin							X		X			GammaGraft
Tendon							X		X			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: No additional information provided.

Proprietary Name(s):