

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: 3009809074	Other FDA Registrations: Blood: Devices: FEI: 3009809074 Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2025 Last Registration Receipt Date: 11/26/2024 Summary Report Print Date: 12/05/2024
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Legal Name and Location: BioTissue Holdings Inc. 8305 NW 27th Street, Suite 101 Doral, Florida 33122 USA Phone: 786-817-6690 Ext.:	Reporting Official: Alpesh Patel, VP, Regulatory Affairs 7300 Corporate Center Drive Suite 700 Miami, Florida 33126 USA Phone: 786-858-4816 Ext. apatel@biotissue.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		X	X		X	X	X	X	X			***See full text on next page.
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
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												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue		X	X		X	X	X	X	X			***See full text on next page.

Additional Information:

Historical Listing:

Amniotic Membrane: AmnioGraft, AmnioGraft ST, CAM360 AmnioGraft, CLARIX 100, CLARIX 100 RT, CLARIX FLO, NEOX 100, NEOX 100 RT, NEOX 100 ST, NEOX FLO, PROKERA, PROKERA Slim, PROKERA Plus, PROKERA Clear.

Umbilical Cord: AmnioGuard, AmnioGuard ST, CLARIX CORD, CLARIX CORD 1K, CLARIX 1K, CLARIX CORD RT, CLARIX GEL, NEOX CORD, NEOX CORD 1K, NEOX 1K, NEOX CORD RT, NEOX RT, NEOX GEL, RESPINA, RESPINA CORD 1K, BTGEL, rBTGEL, Regenesol.

Placenta: AXFILL.

Proprietary Name(s):	Amniotic Membrane	AmnioGraft, AmnioGraft ST, CAM360 AmnioGraft, Clarix 100, Clarix Flo, Neox 100, Neox Flo
	Umbilical Cord Tissue	AmnioGuard, Clarix Cord 1K, Clarix 1K, Clarix Flo, Neox Cord 1K, Neox 1K, Neox Cord RT, Neox RT, Neox Flo

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