

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: 3001451326	Other FDA Registrations: Blood: Devices: FEI: 0001063481 Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2026 Last Registration Receipt Date: 12/02/2025 Summary Report Print Date: 12/15/2025
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Legal Name and Location: Artivion, Inc. 1655 Roberts Blvd., NW Kennesaw, Georgia 30144 USA Phone: 678-290-4531 Ext.:	Reporting Official: Rochelle Maney, VP Quality Systems and Tissue Quality 1655 Roberts Blvd., NW Kennesaw, Georgia 30144 USA Phone: 678-290-4531 Ext. rochelle.maney@artivion.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										01-DEC-23		NeoPatch, Therion
Blood Vessel			X	X	X	X	X	X	X			CryoVein, CryoArtery
Bone												
Cardiac Tissue - non-valved			X	X	X	X	X	X	X			***See full text on next page.
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve			X	X	X	X	X	X	X			CryoValve, CryoValve SG
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium			X	X	X	X	X	X	X			***See full text on next page.
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: NeoPatch/Therion has been discontinued due to a business decision.

Proprietary Name(s):	Cardiac Tissue - non-valved	CryoPatch, CryoPatch SG, CryoArtery, CryoGraft
	Pericardium	CryoPatch, CryoPatch Autologous Pericardium

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