

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,          TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS          DESCRIBED IN 21 CFR 1271.10</b>	<b>FEI:</b> 3001451326	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> FEI: 0001063481 <b>Drugs:</b>	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2023 Last Registration Receipt Date: 12/02/2022 Summary Report Print Date: 12/15/2022
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<b>Legal Name and Location:</b>  Artivion, Inc. 1655 Roberts Blvd., NW  Kennesaw, Georgia 30144 USA  Phone: 678-290-4531 <b>Ext.:</b>	<b>Reporting Official:</b> Rochelle Maney, VP Global Quality 1655 Roberts Blvd., NW Kennesaw, Georgia 30144 USA Phone: 678-290-4531 Ext. rochelle.maney@artivion.com	<b>Satellite Recovery Establishment:</b> No <b>Parent Manufacturing Establishment FEI No.:</b> <b>Testing For Micro-Organisms Only:</b> 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			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:** CryoLife and Misonix entered into an agreement for Misonix to distribute NeoPatch for CryoLife (manufacturer, now named Artivion). Misonix will distribute the amniotic membrane under two brand names, "NeoPatch" and "Therion". NeoPatch and Therion are the same...NeoPatch is not changing in any way.

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

FEI: 3001451326

Legal Name:

Artivion, Inc.