✔ Facility

✔ Products Listing

Annual Registration Successful

Facility: Artivion, Inc., Kennesaw, Georgia, UNITED STATES

You have successfully updated your registration and listing information for 2026.

Your registration will be valid through Dec 31, 2026.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2026.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 9003683.

Facility Information

Registration Number:
1063481

Initial Importer:
N

Facility Name:
Artivion, Inc.

Legal Name:

Address:
1655 Roberts Blvd NW,
Kennesaw, Georgia, 30144, UNITED STATES

DUNS Number:

Foreign Trade Zone:
N

Facility URL:

Other Business Trade Name(s):

Establishment located on a campus:

Owner/Operator Information

Owner/Operator Number:
9003683

Contact Name:

Drew Green

Company:
ARTIVION, INC.

Address: **1655 ROBERTS BLVD., N.W., --**
Kennesaw, GEORGIA, 30144, UNITED STATES

Telephone:
770 - 4193355

Fax:
770 - 5903783

E-mail: **RA_AORTLT@artivion.com**

DUNS Number:

Official Correspondent Information

Contact Name:
Drew Green

Company:
ARTIVION, INC.

Address: **1655 ROBERTS BLVD., N.W., --**
Kennesaw, GEORGIA, 30144, UNITED STATES

Telephone:
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E-mail: **RA_AORTLT@artivion.com**

DUNS Number:

Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities
D367102	K183635		PSQ	Intracardiac patch or pledget, biologically derived	Manufacturer Complaint File Establishment
D265979	K141060		PAW	Nonabsorbable expanded polytetrafluoroethylene surgical suture for chordae tendinae repair or replacement	Complaint File Establishment
D265974	P000037		LWQ	HEART-VALVE, MECHANICAL	Complaint File Establishment

D504080	P210036		LMG	Agent, absorbable hemostatic, non-collagen based	Contract Manufacturer
D367105	K162506		DXZ	PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE	Complaint File Establishment Manufacturer
D367104	K172085		PSQ	Intracardiac patch or pledget, biologically derived	Complaint File Establishment Manufacturer
D272490		510(k) exempt	MDM	INSTRUMENT, MANUAL, SURGICAL, GENERAL USE	Complaint File Establishment
D227523	P970029		MNO	SYSTEM, LASER, TRANSMYOCARDIAL REVASCULARIZATION	Complaint File Establishment Specification Developer
D265981		510(k) exempt	DTI	SIZER, HEART-VALVE, PROSTHESIS	Complaint File Establishment
D265980	K121173		PAW	Nonabsorbable expanded polytetrafluoroethylene surgical suture for chordae tendinae repair or replacement	Complaint File Establishment
D265982		510(k) exempt	LXN	PROBE, TEST, HEART-VALVE	Complaint File Establishment
D006412	P010003		MUQ	Glue, surgical, arteries	Manufacturer Complaint File Establishment
D427487		510(k) exempt	DTJ	HOLDER, HEART-VALVE, PROSTHESIS	Complaint File Establishment
D553086	H230007		QSK	Hybrid stent graft, thoracic aortic lesion treatment	Complaint File Establishment Specification Developer
D208158	K101866		DXZ	PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE	Complaint File Establishment Manufacturer

D208156	K092021		OHA	Heart valve, more than minimally manipulated allograft	Manufacturer Complaint File Establishment
D208157	K110581		FTM	Mesh, surgical	Manufacturer Complaint File Establishment
D272455		510(k) exempt	DWS	INSTRUMENTS, SURGICAL, CARDIOVASCULAR	Complaint File Establishment
D265972	K993288		DXZ	PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE	Manufacturer Complaint File Establishment

Date of Initial Registration: 1997-09-26 09:08:12.0