April 10, 2026

Plasma Surgical, Inc.
% Amy Fowler
Regulatory Counsel
Pathmaker FDA Law, PLLC
1415 Lilac Dr. N
Suite 270
Minneapolis, Minnesota 55422

Re: K253917
Trade/Device Name: ARION ARC System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 13, 2026
Received: March 13, 2026

Dear Amy Fowler:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.04.10 13:55:24 -04'00'

Colin K. Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
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Office of Product Evaluation and Quality
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Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253917

Please provide the device trade name(s).

ARION ARC System

Please provide your Indications for Use below.

The ARION Argon Reposable Coagulator (ARC) System is a plasma surgery system intended for coagulation in open surgery.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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ARION ARC System 510(k) Summary, K# 253917

Date Prepared: April 3, 2026

Submitted by:
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Proprietary or Trade Name: ARION ARC System
Common Name: Argon Reposable Coagulator
Model Number: TBD
Classification: 21 CFR 878.4400 Electrosurgical cutting and coagulation device and accessories
Product Code: GEI

Predicate Device: K121977 Plasma Surgical PlasmaJet System (Version 3-Plus)

Intended Use/Indications for Use: The ARION Argon Reposable Coagulator (ARC) System is a plasma surgery system intended for coagulation in open surgery.

Device Description: The ARION ARC system is a plasma-based surgical device intended for soft tissue coagulation in open surgery. It is based on the design and core functionality of the legally marketed predicate device- PlasmaJet Neutral Plasma Surgery System (K121977), with targeted enhancements/differences, including a reusable handpiece (30 uses) and single-use sterile spacer (s), drape and stem cover that protect the reusable handpiece and assist the user in maintaining a fixed distance to tissue.

Principle of Operation: The ARION ARC system consists of the generator and trolley, which together provides argon gas and a controlled power supply to the reposable handpiece. Within the tip of the handpiece, the argon gas is energized by an internal arc discharge across a series of electrodes.

The resulting pure plasma is a mixture of argon ions and electrons that emerge from the tip of the handpiece as plasma. The plasma quickly releases its energy in two useful forms; first as light that illuminates the surgical field and secondly as heat that is used to coagulate the surface of tissue by creating a thin coagulated layer on the surface of the tissue called a coagulum.

Through a combination of handpiece design and the use of appropriate gas flow and power settings, together with adjusting the distance of the tip from the tissue to be treated, the following tissue effect can be achieved:

Coagulation: When the plasma stream reaches a tissue surface, it gives up its energy as heat and causes coagulation to stop bleeding or modifies the tissue so fluid loss from the tissue surface is reduced. First, the flow of the argon plasma moves fluid away from the tissue surface. Secondly, the energy dissipated from the plasma to the tissue desiccates the tissue to form a series of thin and flexible layers on the tissue surface which may prevent the further expression of fluids, including blood, serous drainage and lymph as examples. A coagulum is created.

The new additions to the ARION ARC System include the reposable handpiece, sterile, single-use spacer and sterile drape. These additions do not alter the fundamental principle of operation or the plasma energy it generates. The spacer allows the user to maintain the optimal working distance for consistent plasma energy delivery. However, it does not impact on the core principles of operation. The plasma generation and energy transfer mechanisms remain unchanged, as the spacer simply acts as a tool for proper positioning without affecting the way the plasma interacts with the tissue. The plasma's behavior—emitting light and heat to coagulate the surface of the tissue remains the same.

Table 1 Comparison between the ARION ARC System and the predicate device

Device Feature	**Subject Device** **K253917**	**Predicate Device** **K121977**
Device Trade Name	ARION ARC System	PlasmaJet
Common Name	Argon Reposable Coagulator (ARC)	Neutral Plasma Surgery System
Classification	21 CFR 878.4400	
Device Class	Class II	
FDA Product Code	GEI	
Device Panel	General and Plastic Surgery	
Indications for Use	The ARION Argon Reposable Coagulator (ARC) System is a plasma surgery system	The PlasmaJet is a neutral plasma surgery system that is designed for

Statement	that is designed for coagulation in open surgery.	cutting, coagulation and the removal of soft tissue by vaporization in open surgery and laparoscopic surgery
Principles of Operation	Both the subject and predicate devices are used for coagulation. Where the predicate device is indicated for both coagulation and surgical applications, the subject device is indicated for exclusive use in coagulation during open surgery. For coagulation, the predicate and subject devices have the same principle of operation for plasma generation and application: Both the ARION ARC system and the PlasmaJet system consist of the generator and trolley, which together provide argon gas and a controlled power supply to the handpiece. While the PlasmaJet handpiece was single use, the ARION ARC system has a reposable handpiece, but both handpiece designs have the same principle of operation. Within the tip of the handpieces, the argon gas is energized by an internal arc discharge across a series of electrodes. The resulting pure plasma is a mixture of argon ions and electrons that emerge from the tip of the handpiece as plasma. The plasma quickly releases its energy in two useful forms; first as light that illuminates the surgical field and secondly as heat that is used to coagulate the surface of tissue by creating a thin coagulated layer on the surface of the tissue called a coagulum. Through a combination of handpiece design and the use of appropriate gas flow and power settings, together with adjusting the distance of the tip from the tissue to be treated, the following tissue effect can be achieved: Coagulation: When the plasma stream reaches a tissue surface, it gives up its energy as heat and causes coagulation to stop bleeding or modify the tissue so fluid loss from the tissue surface is reduced. First, the flow of the argon plasma moves fluid away from the tissue surface. Secondly, the energy dissipated from the plasma to the tissue desiccates the tissue to form a series of thin and flexible layers on the tissue surface which may prevent the further expression of fluids, including blood, serous drainage and lymph as examples. A coagulum is created.	

System components and/or accessories	(1) ARC Generator, formerly referred to as a console (2) ARC Cart, formerly referred to as service module or trolley. (3) ARC Handpiece- Reposable 7cm handpiece (4) Sterile ARC Drape (5) Sterile spacers, 2cm and 7cm, and	(1) PlasmaJet Console (2) PlasmaJet Service Module (3) PlasmaJet Open Surgery Handpieces, Single Use (4) PlasmaJet Laparoscopic Surgery Handpieces, Single Use

	stem cover Optional accessories: (5) ARC Footswitch (6) ARC Handpiece Holder (7) ARC Footswitch Hook	(5) No drape or spacer for handpieces
Technological Characteristics	Argon gas supply: Medical-grade High-purity Argon (≥99.998%)	
	Argon flow rate: 0.2-0.7 l/min	
	Energy source used: 30-60V DC within handpiece	
	Activation Achieved through: Handpiece button or Footswitch	
	Tissue penetration depth: Typically, up to 2.5mm	
	Power: Typically, 20-170W Maximum 300 W	
	Current drawn: The maximum current drawn is 4.5A at 230V and 8A at 120V.	
	Handpiece Design: Reposable, with electrode components designed to meet the reposable requirement of a minimum of 30 uses, each lasting 5 minutes. Cable Material: fully enclosed umbilical cable for wipe down capability	Handpiece Design: Single-use, sterile handpieces for both open and laparoscopic surgery. Cable Material: Umbilical cable bundle enclosed by tubular stocking.
	UI/Display Functionality: Three stages of UI functionality 1. System Startup 2. Session & Power level selection 3. Cooldown/Shutdown System is controlled by physical membrane buttons that correspond to software	UI/Display Functionality: Two stages of UI functionality 1. System Startup 2. Plasma Use, Mode select & Power level select System is controlled by physical membrane buttons that correspond to

	elements on screen. System setup includes gas connection, handpiece connection, coolant fill, and drape attachment. Session & Power Level select screens allow user to Start/End sessions, toggle between Low/High power levels. Cooldown/Shutdown screens prompt user to allow system to cool down prior to next session and provides instructions on how to shut down system.	software elements on screen. System setup includes gas connection, handpiece connection, and coolant fill. Plasma Use, Mode Select & Power Level select screens allow user to activate plasma, change modes (Low/High/Ultra), adjust Power Levels (0-120 for cut, 0-100 for coagulation).
	Accessories: The ARC System introduces these accessories: -ARC Footswitch, Single Pedal (Coagulation only) -ARC Handpiece Holder -ARC Side Basket -ARC Footswitch Hook	N/A
	Usage Tracking Functionality: ARC Handpieces contain software and hardware that tracks and stores the amount of sessions that are available for use by a physician. The session is a preset allotment of active plasma time. The number of sessions and allotted session time are determined by the handpiece profile configured at time of manufacture.	N/A
Product Shelf-life	Handpieces: The shelf-life of the ARC Handpiece is 3 years. Sterile Drape in blister pack - Shelf life of 2 years.	Handpieces: The handpieces for both open-surgery and laparoscopic-surgery are sterile, single-use, with a shelf-life of 3 years.

	Sterile spacers and stem cover in pouch – shelf life of 1 years Other Components: The generator, cart, footswitch, and handpiece holder are non-sterile, reusable components and do not have a shelf-life associated with them.	Other Components: The console and service trolley are non-sterile, reusable components and do not have a shelf-life associated with them.

Performance/Bench Testing Data: The following testing was performed in support of the substantial equivalence determination:

- Biocompatibility ISO 10993-1, -5, -9, -10, -11, -12, -23
  - USP Rabbit Pyrogen Testing
  - Intracutaneous Irritation
  - Systemic Toxicity
  - ISO Guinea Pig Maximization Sensitization
  - Cytotoxicity
- Sterilization Validation ISO 11135
  ISO 11138-3
  ISO 17665-1
  ISO 11607-1
  ISO 11607-2
- Reprocessing validation ANSI AAMI ST98
  - Use-Life Validation of Reprocessing
- Cleaning and Disinfection Validation
- Design Verification Testing:
  - Functional Testing
  - Spectroscopy
  - Calorimetry
  - Leak Testing
- Software validation and verification
- Electrical Safety IEC 60601-1-1
- Electromagnetic Compatibility IEC 60601-1-2
- Human Factors/Usability IEC 62366-1
- Accelerated Aging/Stability
- Package Performance ASTM 4169-22
  ASTM F88/F88M-23

Animal Testing/Human Clinical Data: No animal or human clinical test data supports this 510(k).

Conclusion: The information provided above supports that the ARION ARC System is substantially equivalent to the predicate device. Although minor differences in design and technology exist between the subject and predicate device, the testing supports that these differences do not raise any new questions of safety and effectiveness.