December 31, 2025

ARC Trauma, LLC
Dr. Jeffrey Williams
2310 Mt. Carmel Rd.
Jamestown, Ohio 45335

Re: K243627
Trade/Device Name: Laryngoscope Junctional-Arterial Restriction Clamp (L-ARC); Arterial Restriction Clamp (ARC)
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: DXC
Dated: June 3, 2025
Received: June 5, 2025

Dear Dr. Jeffrey Williams:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Katherine N. Trivedi -S
Digitally signed by Katherine N. Trivedi -S
Date: 2025.12.31 09:17:01 -07'00'

Katherine Trivedi
Assistant Director
DHT2B: Division of Circulatory Support, Structural, and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

Laryngoscope - Arterial Restriction Clamp (L-ARC);
Arterial Restriction Clamp (ARC)

Indications for Use *(Describe)*

The L-ARC is indicated for use in the battlefield to control difficult bleeds inguinal area. The L-ARC is also indicated for use in the battlefield as a last resort for life threatening bleeds of the carotid artery.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #:

510(k) Summary

Prepared on: 2025-09-30

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	ARC Trauma, LLC
Applicant Address	2310 Mt. Carmel Rd. Jamestown OH 45335 United States
Applicant Contact Telephone	972-746-7471
Applicant Contact	Dr. Jeffrey Williams
Applicant Contact Email	jswsurgery@gmail.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Laryngoscope - Arterial Restriction Clamp (L-ARC); Arterial Restriction Clamp (ARC)
Common Name	Vascular clamp
Classification Name	Clamp, Vascular
Regulation Number	870.4450
Product Code(s)	DXC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K141685	Combat Ready Clamp "CRoC"	DXC

Device Description Summary

21 CFR 807.92(a)(4)

The Laryngoscope-Arterial Restriction Clamp is designed to be used by military medical personnel in the battlefield. The device is designed to control bleeding in the neck and inguinal areas where standard tourniquets cannot be used. The device can be used instead of manual pressure, allowing the medic to attend to other injuries or soldiers. The Laryngoscope-Arterial Restriction Clamp is use to control areas of difficult bleeding for up to 4 hours until the injured soldier can be transferred to evacuation personnel for further treatment or until the device can be converted to conventional dressings. The device can be used to directly visualize the oropharynx to assist with intubation in the soldier with a compromised airway.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The L-ARC is indicated for use in the battlefield to control difficult bleeds inguinal area. The L-ARC is also indicated for use in the battlefield as a last resort for life threatening bleeds of the carotid artery.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Base on technological characteristics, the Laryngoscope-Arterial Restriction Clamp has been shown to be substantially equivalent to the predicate device, the Combat Ready Clamp.

Technological Comparison

21 CFR 807.92(a)(6)

The Laryngoscope - Arterial Restriction Clamp as similar technological components as the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The Laryngoscope-Arterial Restriction Clamp was tested via bench testing to show that it could provide pressures equivalent to the predicate device.

Studies on live patients were not carried out due to the nature of the injury being studied.

The Laryngoscope-Arterial Restriction Clamp was also tested with a perfused cadaver model to show that it was capable of stopping simulated vessel blood pressure.