October 7, 2025

Acotec Scientific Co., Ltd.
% Sara Toyloy
President and Principal Consultant
Fabrica Consulting, LLC
73 Lincoln Drive
Sausalito, California 94965

Re: K250688
Trade/Device Name: Cedar™ Endovenous Radiofrequency Catheter (ERA-C70-US); Cedar™ Endovenous Radiofrequency Catheter (ERA-C30-US); Endovenous Radiofrequency Generator (ERA-G5-US)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 7, 2025
Received: September 8, 2025

Dear Sara Toyloy:

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2025.10.07 22:07:08 -04'00'

Colin Kejing Chen
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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)*

K250688

Device Name

Cedar™ Endovenous Radiofrequency Catheter (ERA-C70-US);
Cedar™ Endovenous Radiofrequency Catheter (ERA-C30-US);
Endovenous Radiofrequency Generator (ERA-G5-US)

Indications for Use *(Describe)*

Cedar™ Endovenous Radiofrequency Catheters:
Cedar™ Endovenous Radiofrequency Catheters are intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

Endovenous Radiofrequency Generator:
The Endovenous Radiofrequency Generator is used with radiofrequency catheters intended for vessel coagulation.

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.

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510(k) Summary (K250688)

Submitter Name, Address and Contact:

Submitter: Acotec Scientific Co., Ltd.
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Phone: +1 (415) 297-8826

Date Prepared: October 7, 2025

Device Name and Classification:

Trade/Proprietary Name:	Cedar™ Endovascular Radiofrequency Catheters Endovenous Radiofrequency Generator
Common Name:	Electrosurgical Device
Classification Name:	Electrosurgical cutting and coagulation device and accessories, 21 CFR 878.4400 – Class II
Product Code:	GEI
Legally Marketed Predicate Device:	ClosureFAST™ Radiofrequency Catheter (K111887) Models: CF7-7-60, CF7-7-100, CF7-3-60 ClosureRFG™ Radiofrequency Generator (K141858) Model: RFG3

Device Description:

Like the predicate device, the Cedar Endovenous Radiofrequency Catheters are sterile, single use, disposable radiofrequency (RF) catheters with an integrated connection cable. The catheter has a 7F profile with a heating element (coil) available in two lengths, 3cm and 7cm with a 2.15mm diameter. The catheters include a 60cm working length and catheter positioning is achieved via the

heating element with engraved marker. The catheter's function is to provide thermal energy to the desired treatment site through radiofrequency heating from the catheter heating element. The Cedar catheter is designed to be used with the Acotec Endovenous Radiofrequency Generator which is designed to provide controlled delivery of RF energy.

The Endovenous Radiofrequency Generator is designed to provide controlled delivery of radiofrequency (RF) energy to RF catheters marketed by Acotec intended for vessel coagulation. The RF generator supplies and controls the RF energy delivered to the catheter and measures and displays RF output power and elapsed time of RF delivery. The generator also interfaces with a sensor in the catheter to provide a continuous display of measured patient temperature prior to and during RF delivery.

Indications for Use:

Cedar™ Endovenous Radiofrequency Catheters are intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

The Endovenous Radiofrequency Generator is used with radiofrequency catheters intended for vessel coagulation.

Technological Characteristics and Product Feature Comparison:

The subject devices have the following same characteristics as the predicate devices:

Catheter

- Same indications for use
- Same sterilization method
- Same method of access
- Same vessel closure effect
- Same target vessel

Catheter and Generator

- Same Energy Type
- Same Environment of use
- Same Electrical Safety
- Same Electromagnetic Compatibility
- Same Principle of Operation
- Same Main Physical Performance Requirement
- Same Nature of body contact and contact duration
- Same Treatment Time
- Same Thermal Damage

Table 1: Subject and Predicate Device Comparison

Parameters	Subject Device		Predicate Device	
Default Temperature Setting	120℃		120℃	
Treatment Time	20s		20s	
Heating Element Length	30mm	70mm	30mm	70mm
Inserted Catheter Length	60cm		60cm	
Introducer Sheath (Min. ID size)	7F (2.3mm)		7F (2.3mm)	
Guidewire Compatibility	0.025" guidewire		0.025" guidewire	

The following outlines the technological characteristics that are considered substantially equivalent:

Catheters:
- Dimensions
- Materials of Construction
- DC Impedance
- Shelf-Life

Generator:
- Indications for Use (predicate can be used with Stylet)
- Feedback (works with Stylet)
- Lifetime
- Load (RF Catheters)

Performance Data

To demonstrate substantial equivalence of the subject device to the predicate device, the following design verification and validation testing were performed:

Biocompatibility Testing:
Biocompatibility testing was conducted on the Cedar™ Endovenous Radiofrequency Catheters in accordance with FDA guidance document, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" " and demonstrates that the Cedar™ Endovenous Radiofrequency Catheters meet biological safety requirements for externally communicating medical devices with circulating blood contact for less than 24 hours.

Table 2: Summary of Biocompatibility Testing

Test	Test Method Summary	Conclusion
Acute Systemic Toxicity	Per ISO 10993-11: 2017	Pass: No evidence of acute systemic toxicity.
ASTM Partial Thromboplastin	Per ISO 10993-4: 2017	Pass: No abnormal clotting
Compliment Activation	Per ISO 10993-4: 2017	Pass: Non-activator
Cytotoxicity – MEM Elution	Per ISO 10993-5: 2009	Pass: Non-cytotoxic
Hemolysis	Per ISO 10993-4: 2017	Pass: Non-hemolytic
Intracutaneous Reactivity	Per ISO 10993-10: 2021	Pass: Non-reactive

Test	Test Method Summary	Conclusion
In Vivo Thrombogenicity	Per ISO 10993-4: 2017	Pass: Non-Thrombogenic
Platelet Leukocyte Count	Per ISO 10993-4: 2017	Pass: Non-Thrombogenic
Pyrogenicity	Per ISO 10993-11: 2017	Pass: Non-pyrogenic
Sensitization	Per ISO 10993-10: 2021	Pass: Non-sensitizing

Electromagnetic Compatibility (EMC):
Electromagnetic compatibility (EMC) testing were conducted on the Endovenous Radiofrequency Generator and the Cedar™ Endovenous Radiofrequency Catheters. The system complies with the IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020, ANSI/AAMI/IEC 60601-1-2:2014/A1:2021 standard for EMC.

Electrical, Mechanical and Thermal (EMT) Safety Testing:
Electrical, Mechanical and Thermal (EMT) Safety Testing was conducted on the Endovenous Radiofrequency Generator and Cedar™ Endovenous Radiofrequency Catheters according to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1: 2012, ES60601-1:2005/AMD2:2021 and IEC 60601-2-2: 2017, ANSI/AAMI/IEC 60601-2-2:2017. This testing confirmed that the Cedar™ Endovascular Radiofrequency Catheters and the Endovenous Radiofrequency Generator fulfil the requirements as outlined in the standards.

Software Verification and Validation Testing:
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." and IEC 62304 Edition 1.1 2015-06.

Animal Testing:
Animal testing was conducted on the Cedar™ Endovascular Radiofrequency Catheters with the Endovenous Radiofrequency Generator to demonstrate the safety and feasibility of the Cedar™ Endovascular Radiofrequency Catheters and demonstrated that there were no new risks associated with the test articles compared to the control.

Other Non-clinical Verification and Validation Testing:
The Cedar™ Endovascular Radiofrequency Catheters were subjected to verification and validation testing including dimensional, tensile strength and sterilization validation.

The Cedar™ Endovascular Radiofrequency Catheters and the Endovenous Radiofrequency Generator were subjected to verification and validation testing including package integrity, environmental and simulated use testing.

The results of the verification and validation testing demonstrate that the Cedar Endovenous Radiofrequency System meets acceptance criteria and has comparable performance to the

predicate devices and supports the safety and effectiveness of both the Cedar Endovenous Radiofrequency Catheters and the Endovenous Radiofrequency Generator.

Clinical Testing

A prospective, multicenter, randomized controlled clinical study was conducted to verify the safety and effectiveness of the Endovenous Radiofrequency Catheters and Endovenous Radiofrequency Generator in the treatment of varicose veins of lower limbs.

The Endovenous Radiofrequency Generator and Cedar Endovenous Radiofrequency Catheters produced by Acotec Scientific Co., Ltd. demonstrated excellent clinical safety and were non-inferior to the control predicate devices, the ClosureRFG™ Radiofrequency Generator and ClosureFAST™ Endovenous Radiofrequency Ablation (RFA) Catheter produced by Medtronic Inc. in terms of clinical efficacy in the treatment of varicose veins of the lower limbs.

Therefore, the results of this study demonstrate the safety and effectiveness of the Cedar Endovenous Radiofrequency Catheters and Endovenous Radiofrequency Generator.

Substantial Equivalence Conclusion

Based on the device comparison and results of non-clinical and clinical testing, the Cedar™ Endovenous Radiofrequency System (catheters and generator) is substantially equivalent to the predicate devices – ClosureFast™ Radiofrequency Catheter (K111887) and ClosureRFG™ Radiofrequency Generator (K141858). The subject devices incorporate comparable technological characteristics, demonstrate equivalent safety and performance, and do not raise new questions of safety or effectiveness.