March 27, 2026

Aventix Medical, Inc.
% David Locke
Regulatory Consultant
Albatross Regulatory Consulting
25606 Corte Botella
Murrieta, California 92563

Re: K260255
Trade/Device Name: AVENTIX PFX System (PFX01); NOVOCLEAR Device (CLR001)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 27, 2026
Received: January 28, 2026

Dear David Locke:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

JOYCE C. LIN -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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.	K260255

Please provide the device trade name(s).

AVENTIX PFX System (PFX01);
NOVOCLEAR Device (CLR001)

Please provide your Indications for Use below.

The AVENTIX™ PFX System is an electrosurgical system intended to generate Pulsed Field Energy (PFE) for use with the NOVOCLEAR™ Device. The AVENTIX™ PFX System is indicated for use in small clinics, offices and/or hospital environments.

The NOVOCLEAR™ Device is indicated for use in otorhinolaryngology (ENT) surgery for the destruction of soft tissue in the nasal airway, including the posterior nasal nerve distribution in patients with chronic rhinitis.

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)

510(K) SUMMARY

[807.92(a)(1)] Submitter Information

Applicant:
Aventix Medical Inc.
23282 Mill Creek Dr.
Suite 350
Laguna Hills, CA, 92653
Tel.: 201-819-8685
Fax: 702-780-6912

Contact Person:
David Locke
Regulatory Consultant
Phone: 419-233-2611
albatrossregulatory@yahoo.com

Authored by:
David Locke
Regulatory Consultant
Phone: 419-233-2611

Date Summary Prepared: March 22, 2026

[807.92(a)(2)] Name of Device

Device Trade Name:	AVENTIX™ PFX System (PFX01) NOVOCLEAR™ Device (CLR001)
Device Common Name:	Electrosurgical system and device
Regulations Name:	Electrosurgical, cutting & coagulation & accessories
Regulation Number:	21 CFR 878.4400
Device Classification:	Class II
Product Code:	GEI
Primary Review Panel:	General and Plastic Surgery

[807.92(a)(3)] Legally Marketed Devices

Primary Predicate Device: Aerin Medical Inc. / RhinAer® Stylus (K221907)
Secondary Predicate: Aerin Medical Inc. / Aerin Console (K162810)

[807.92(a)(4)] Device Description

Device Description:

The AVENTIX™ PFX System and NOVOCLEAR™ Device include the following components:

1) NOVOCLEAR™ Device - a single use, hand-held device capable of delivering pulsed field energy (PFE) to targeted tissue. The NOVOCLEAR™ Device consists of a handle, a dome-like electrode and an electrical connector. The dome-like electrode delivers PFE and is angled to approximately 60 degrees, to aid access to the targeted tissue. An electrical connector is used to connect the NOVOCLEAR™ Device to the AVENTIX™ Generator.
2) AVENTIX™ Generator - generates predefined PFE output, which is delivered to the NOVOCLEAR™ Device dome-like electrode tip.
3) AVENTIX™ Controller – Performs validation of the NOVOCLEAR™ Device prior to use, changes the status of the Generator between armed and disarmed, and receives and displays parameters from the generator to the user.
4) Footswitch – for selective activation by the user to initiate PFE output.

The NOVOCLEAR™ Device delivers pulsed field energy (PFE) to soft tissues in the nasal airway, including the posterior nasal nerve distribution. Non-clinical testing was performed to support safety and performance for the labeled use.

[807.92(a)(5)] Intended Use / Indications for Use

Indications for Use:

The AVENTIX™ PFX System is an electrosurgical system intended to generate pulsed field energy (PFE) for use with the NOVOCLEAR™ Device. The AVENTIX™ PFX System is indicated for use in small clinics, offices and/or hospital environments.

The NOVOCLEAR™ Device is indicated for use in otorhinolaryngology (ENT) surgery for the destruction of soft tissue in the nasal airway, including the posterior nasal nerve distribution in patients with chronic rhinitis.

[807.92(a)(6)] Technical Characteristics

System Characteristics:

The AVENTIX™ PFX System generates a predefined pulsed field energy (PFE) waveform for delivery through the NOVOCLEAR™ Device to targeted nasal tissue for the labeled use. The system includes a generator, controller with user interface, and a footswitch for activation. The NOVOCLEAR™ Device connects to the generator and delivers energy through a dome-like electrode tip.

The AVENTIX™ PFX System requires NOVOCLEAR™ Device validation prior to use.

Different Technological Characteristics:

The AVENTIX™ PFX System and NOVOCLEAR™ Device are radiofrequency-based devices that deliver pulsed field energy to produce a non-thermal tissue effect, while the predicate device produces a thermal tissue effect.

[807.92(b)] Non-Clinical Tests Summary & Conclusions

Non-clinical Performance Data:

The AVENTIX™ PFX System and NOVOCLEAR™ Device were tested to ensure that the product functions in accordance with the device design specifications related to substantial equivalence in terms of device safety and effectiveness.

The following non-clinical tests were performed:

1. System Design Verification – The AVENTIX™ PFX System and NOVOCLEAR™ Device were tested to ensure compatibility of system components during pulsed field energy (PFE) delivery.
2. Design Validation – The AVENTIX™ PFX System and NOVOCLEAR™ Device functions and interfaces were evaluated with surgeons under simulated use and were shown to meet user needs for delivery of PFE to soft tissue in the nasal airway, including the posterior nasal nerve distribution, in patients with chronic rhinitis.
3. Software Validation – Software functions supporting the user interface, device validation, system communications, and energy delivery configuration were verified and validated and shown to meet software requirements and specifications.
4. Usability Engineering – Use-related risks were evaluated, and mitigations were verified/validated through usability testing.
5. Biocompatibility – The NOVOCLEAR™ Device was evaluated per applicable ISO requirements for the contact type and duration, including cytotoxicity, sensitization, and irritation, and met acceptance criteria.
6. Sterilization Validation - The NOVOCLEAR™ Device was validated for irradiation sterilization and demonstrated a Sterility Assurance Level (SAL) of 10^{-6} using E-beam radiation.
7. Preclinical – The NOVOCLEAR™ Device was evaluated under clinically relevant conditions to support safety and performance characterization. In 6 pigs, NOVOCLEAR-treated lesions were compared with predicate device lesions using necropsy and histologic evaluation at approximately 4 hours, 7 days, and 28 days post-treatment to assess lesion size and tissue injury relative to the predicate device.
8. Shelf-life and Packaging – Packaging integrity and shelf-life testing (including aging, distribution simulation, and post-aging functional verification) were performed and the device met acceptance criteria.
9. Cybersecurity – Cybersecurity risk controls were implemented and verification/validation activities were performed to support the confidentiality, integrity, and availability of system functions.

Substantial Equivalence Table

Characteristics	Predicate Device: (K221907) Aerin Medical Inc. / RhinAer® Stylus	Secondary Predicate: Device (K162810) Aerin Medical Inc / Aerin Console	Subject Device: AVENTIX™ PFX System and the NOVOCLEAR™ Device	Notes
Indications for Use	The RhinAer Stylus is indicated for use in otorhinolaryngology (ENT) surgery for the destruction of soft tissue in the nasal airway, including in posterior nasal nerve regions in patients with chronic rhinitis.	Aerin Console: The Aerin Console is an electrosurgical system intended to generate radiofrequency electrical current for the use of an ARC Stylus (e.g. InSeca ARC Stylus). The Aerin Console is indicated for use in small clinic, office or hospital environments.	The AVENTIX™ PFX System is an electrosurgical system intended to generate pulsed field energy (PFE) for use with the NOVOCLEAR™ Device. The AVENTIX™ PFX System is indicated for use in small clinics, offices and/or hospital environments. The NOVOCLEAR™ Device is indicated for use in otorhinolaryngology (ENT) surgery for the destruction of soft tissue in the nasal airway, including the posterior nasal nerve distribution in patients with chronic rhinitis.	Same, except the subject device's radiofrequency-based system delivers pulsed field energy.
Use Environment	Small clinic, office or hospital environments.	Small clinic, office or hospital environments.	Small clinic, office or hospital environments.	Same

Patient Population	Patients with chronic rhinitis.	N/A	Patients with chronic rhinitis.	Same
Device Class	Class II	Class II	Class II	Same
Product Code	GEI	GEI	GEI	Same
Sterilization Method	EtO	N/A	Irradiated	Meets Sterility Assurance Level (SAL) 10^{-6}
Packaging	Tray	N/A	Tray card	Same
Design Configuration	Integrated cable, handle, and electrode	N/A	Integrated cable, handle, and electrode	Same
Power	4W	3-5W	2-4W	Same
Generator Compatibility	Aerin Console	Aerin Console	AVENTIX PFX Generator	Same
Shaft Shape	Straight with diameter step down	N/A	Straight with diameter step down	Same
Shaft Diameter - Proximal	0.12 inches	N/A	0.079 inches	Smaller to support access to targeted tissue.
Shaft Diameter - Distal	0.083 inches	N/A	0.059 inches	Smaller to support access to targeted tissue.
Tip Tilt Angle	10-degree tilt	N/A	60-degree	Dome-like tip design supports access to targeted tissue

Conclusion: The AVENTIX™ PFX System and NOVOCLEAR™ Device are substantially equivalent to the predicate device(s) based on a comparison of the intended use, indications for use, and technological characteristics. The differences in technological characteristics do not raise new safety and effectiveness concerns, as supported by results of non-clinical testing.