May 29, 2026

Entire Medical , Ltd.
% Glenn Stiegman
Sr. VP, Clinical, Quality, and Regulatory Affairs
Mcra, LLC
803 7th St. NW, 3rd Floor
Washington, District of Columbia 20001

Re: K261202
Trade/Device Name: ENTire IRE System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 13, 2026
Received: April 13, 2026

Dear Glenn Stiegman:

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,

JAMES H. JANG -S

Digitally signed by JAMES H. JANG -S
Date: 2026.05.29 18:30:27 -04'00'

For
Colin Kejing Chen, Ph.D.
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

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.	K261202

Please provide the device trade name(s).

ENTire IRE System

Please provide your Indications for Use below.

The ENTire IRE System is indicated for the surgical ablation of soft tissue, specifically for otorhinolaryngology (ENT) indications.

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

Device Trade Name: ENTire IRE System

Manufacturer: ENTire Medical Ltd.
11 Ha'hoshlim St.
Herzliya 4672411, Israel

Submission Contact: Glenn Stiegman
Sr. VP, Clinical, Quality, and Regulatory Affairs
MCRA, LLC
803 7th Street NW, Third Floor Washington, DC 20001
Phone: (202) 552-5803
Email: gstiegman@mcra.com

Date Prepared: May 8, 2026

Regulation Number: § 878.4400

Classification Name: Electrosurgical cutting and coagulation device and Accessories

Class: II

Product Code: GEI

Predicate Device: ENTire IRE System (ENTire Medical Ltd.; K251996)

Indications For Use:
The ENTire IRE System is indicated for the surgical ablation of soft tissue, specifically for otorhinolaryngology (ENT) indications.

Device Description:
The ENTire IRE System includes a reusable electrosurgical generator activated by a foot pedal and single-use handpieces which are provided sterile. The ENTire IRE System utilizes irreversible electroporation ("IRE"), a nonthermal ablation technology that delivers high-voltage, low-energy electrical pulses to tissue via bipolar electrodes. The system generates irreversible nanopores in the cell membranes, altering the cell membrane characteristics, and inducing apoptosis. The dead cells are then resorbed leading to tissue reduction.

Substantial Equivalence:

The indications for use, materials, technological characteristics, principles of operation, and performance of the subject ENTire IRE System are substantially equivalent to those of the predicate device.

To support a determination of substantial equivalence, ENTire Medical performed verification and validation testing demonstrating the subject device performs as intended. Based on the data provided, any differences between the subject and cleared ENTire IRE Systems do not raise new or different questions of safety and effectiveness.

	Subject Device	Predicate Device (K251996)
Trade Name and Manufacturer	ENTire IRE System, ENTire Medical Ltd.	ENTire IRE System, ENTire Medical Ltd.
Regulation Number	878.4400	878.4400
Product Code	GEI	GEI
Technology	Irreversible Electroporation ("IRE")	Irreversible Electroporation ("IRE")
Indications for Use	The ENTire IRE System is indicated for the surgical ablation of soft tissue, specifically for otorhinolaryngology (ENT) indications.	The ENTire IRE System is indicated for the surgical ablation of soft tissue, specifically for otorhinolaryngology (ENT) indications.
Components	• ENTire IRE Generator (reusable) • Sterile, disposable, single use handpiece electrodes • Non-sterile foot switch (reusable) • Non-sterile power cord (reusable)	• ENTire IRE Generator (reusable) • Sterile, disposable, single use handpiece electrodes • Non-sterile foot switch (reusable) • Non-sterile power cord (reusable)
Output Frequency (kHz)	333 - 1,000	200 - 1,000
Number of Bursts per Application	Up to 40	Up to 40
Voltage (kV)	1.3 - 1.5	1.3 - 1.5
Pulse Width (µsec)	1 - 3	1 - 5
Application Length (msec)	Up to ~150	Up to ~150
Max Power Output (W)	2.7 @ 115 Ω	4.0 @ 115 Ω
Generator Power Input (VAC)	100 - 240	100 - 240
Energy Output	Bipolar	Bipolar
Exposure Length (mm)	6, 8.5, 11.5 (tonsil); 8 (turbinate)	6, 8.5, 11.5 (tonsil); 8 (turbinate)
Outer Width (mm)	4.5 (tonsil); 2.2 (turbinate)	4.5 (tonsil); 2.2 (turbinate)
Material Shaft	Stainless steel (active electrode tip made of Stainless steel 316L)	Stainless steel (active electrode tip made of Stainless steel 316L)

	Subject Device	Predicate Device (K251996)
Shaft Isolation	Nylon (Polyamide 11)	Nylon (Polyamide 11)
Sterilization	Steam	Steam
Activation Method	Foot Pedal	Foot Pedal

Performance Testing Summary:

The following performance data was referenced or provided in support of the substantial equivalence determination:

Electromagnetic Compatibility (EMC) and Electrical Safety Testing

The subject ENTire IRE System complies with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-2, IEC 60601-4-2, IEC 60601-1-6, IEC 62304, IEEE 1016, and IEC 62366-1. All electrical safety and EMC tests passed.

Software Verification and Validation Testing

Software verification and validation testing were conducted and enhanced documentation was provided as recommended by FDA's Guidance, "*Content of Premarket Submissions for Device Software Functions*", issued on June 14, 2023. The software validation ensured that all software requirements, as defined in the Software Requirements Specification (SRS), were systematically verified through comprehensive test cases. The validation process confirmed that the software functions as intended under expected operating conditions, met all predefined acceptance criteria, and supports the safety and effectiveness of the device.

Summary

The performance testing conducted for the subject ENTire IRE System demonstrated that the device performs as intended in its use for soft tissue reduction in ENT procedures. These results provide strong evidence that the ENTire IRE System does not raise new questions of safety or effectiveness for its intended indications.

Conclusion:

Based on the information provided in this 510(k) Premarket Notification, the subject ENTire IRE System is substantially equivalent to its predicate device, and is as safe, as effective, and performs as well as the predicate device.