



January 14, 2026

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

Re: K251996

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: December 12, 2025

Received: December 15, 2025

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 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](mailto: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: 2026.01.14  
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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.

K251996

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Please provide the device trade name(s).

?

ENTire IRE System

Please provide your Indications for Use below.

?

The Irreversible Electroporation (IRE) System Generator 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 (Part 21 CFR 801 Subpart D)  
 Over-The-Counter Use (21 CFR 801 Subpart C)

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### *510(k) Summary*

<b>Device Trade Name:</b>	ENTire IRE System
<b>Manufacturer:</b>	ENTire Medical Ltd. 11 Ha'hoshlim St. Herzliya 4672411, Israel
<b>Contact:</b>	<b>Glenn Stiegman</b> Sr. VP, Clinical, Quality, and Regulatory Affairs MCRA, LLC 803 7 <sup>th</sup> Street NW, Third Floor Washington, DC 20001 Phone: (202) 552-5803 Email: <a href="mailto:gstiegman@mcra.com">gstiegman@mcra.com</a>
<b>Prepared by:</b>	MCRA, LLC 803 7 <sup>th</sup> Street, NW, 3 <sup>rd</sup> Floor Washington, DC 20001 Office: 202.552.5800
<b>Date Prepared:</b>	14 JAN 2026
<b>Classifications:</b>	§ 878.4400 – Electrosurgical cutting and coagulation device and accessories
<b>Class:</b>	II
<b>Product Codes:</b>	GEI
<b>Primary Predicate:</b>	WEREWOLF™ COBLATION™ System with the COBLATION™ HALO™ Wand (K192027)
<b>Reference Device:</b>	CellFX Percutaneous Electrode System (K233705)

#### **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.

**Predicate Device:**

ENTire Medical submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, ENTire IRE System is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate: WEREWOLF™ COBLATION™ System with the COBLATION™ HALO™ Wand (K192027)

Reference Device: CellFX Percutaneous Electrode System (K233705)

**Substantial Equivalence:**

To support a determination of substantial equivalence, ENTire Medical performed verification and validation testing demonstrating the subject device performs as intended; therefore, even though the ENTire IRE System has different technological characteristics than the primary predicate device, based on the data provided, the ENTire IRE System does not raise any new or different questions of safety and effectiveness.

	<b>Subject Device</b>	<b>Predicate Device (K192027)</b>	<b>Reference Device (K233705)</b>
<b>Trade Name</b>	ENTire IRE System	WEREWOLF COBLATION System, COBLATION HALO Wand	CellFX Percutaneous Electrode System

	Subject Device	Predicate Device (K192027)	Reference Device (K233705)
<b>Regulation</b>	878.4400	878.4400	878.4400
<b>Product Code</b>	GEI	GEI	GEI
<b>Technology</b>	Irreversible Electroporation (“IRE”)	Radiofrequency (RF)	Irreversible Electroporation (“IRE”)
<b>Indications for Use</b>	<p>The ENTire IRE System is indicated for the surgical ablation of soft tissue, specifically for otorhinolaryngology (ENT) indications.</p>	<p>The WEREWOLF COBLATION System controller is indicated for the resection, ablation and coagulation of soft tissues and hemostasis of blood vessels in the following otorhinolaryngology (ENT) procedures:</p> <ul style="list-style-type: none"> <li>- Tonsillectomy (Including Palatine Tonsils)</li> <li>- Adenoidectomy</li> <li>- Uvulopalatopharyngoplasty (UPPP)</li> <li>- Traditional Uvulopalatoplasty (RAUP)</li> <li>- Nasal Airway Obstruction</li> <li>- Submucosal Palatal Shrinkage</li> <li>- Submucosal Tissue Shrinkage</li> <li>- Nasal Airway Obstruction by Reduction of Hypertrophic Nasal Turbinates</li> <li>- Reduction of Turbinates for the Treatment of Nasal Airway Obstruction</li> <li>- Nasopharyngeal/Laryngeal Indications Including Tracheal Procedures</li> <li>- Mastoidectomy</li> <li>- Myringotomy with Effective Hemorrhage Control</li> <li>- Papilloma Keloids</li> <li>- Nasopharyngeal/Laryngeal Procedures</li> <li>- Polypectomy</li> <li>- Laryngeal Polypectomy</li> <li>- Laryngeal Lesion Debulking</li> <li>- Cysts</li> <li>- Tumors</li> <li>- Neck Mass</li> <li>- Head, Neck, Oral, and Sinus Surgery</li> </ul>	<p>The CellFX® Percutaneous Electrode System is intended for ablation of soft tissue in percutaneous and intraoperative surgical procedures. It is not intended for use in cardiac procedures.</p>

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	Subject Device	Predicate Device (K192027)	Reference Device (K233705)
		<p>- Tissue in the Uvula/ Soft Palate for the Treatment of Snoring</p> <p>Indications for use – COBLATION™ HALO™ Wand</p> <p>The COBLATION HALO Wand, used with the WEREWOLF COBLATION System, is indicated for ablation, resection and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including: tonsillectomy, adenoidectomy, and uvulopalatopharyngoplasty (UPPP). It is intended for procedures using a conductive media, such as normal saline or Ringer's lactate.</p>	
<b>Components</b>	<p>ENTIRE IRE Generator (re-usable)</p> <p>Sterile, disposable, single use Handpiece electrodes</p> <p>Non-sterile Foot switch (re-usable)</p> <p>Reusable, non-sterile power cord</p>	<p>A bipolar, radiofrequency (RF) generator (Controller) with Integrated Fluid Module and Operational Interface Screen</p> <p>Re-usable, non-sterile Foot Control (wired or wireless)</p> <p>Sterile, disposable, single-use COBLATION Wand(s)</p> <p>Reusable, non-sterile power cord</p>	<p>RF Generator, Active Electrode, Adapter, Footswitch</p>
<b>Output Frequency</b>	200-1,000 kHz	100 kHz	1-10 Pulses per second
<b>Number of Bursts per Application</b>	Up to 40 bursts	N/A	40 bursts
<b>Voltage</b>	1.3 - 1.5 kV	340 V <sub>rms</sub>	800V to 15kV
<b>Pulse Width (in seconds)</b>	1 - 5μs	N/A	100- 500ns
<b>Application Length</b>	Up to ~150ms	N/A	4000ms
<b>Max Power Output</b>	4.0W @ 115 Ω	400 W @ 250 Ω	15 Watts
<b>Generator Power Input</b>	100-240 VAC	100-240 VAC, 50/60 Hz, 16A	100-240 VAC
<b>Energy Output</b>	Bipolar	Bipolar	Bipolar
<b>Handpiece Length</b>	180 – 240 mm	9.0 inches (228.6mm)	95mm

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	Subject Device	Predicate Device (K192027)	Reference Device (K233705)
<b>Exposure Length</b>	6mm, 8.5mm, 11.5mm (tonsil); 8mm (turbinate)	4.04mm	14mm
<b>Outer Diameter/Width</b>	4.5mm width (tonsil); 2.2mm width (turbinate)	3.45mm	2.4mm
<b>Material Shaft</b>	Stainless steel (active electrode tip made of Stainless steel 316L)	Grade 304 Stainless Steel Electrode: Tungsten Alloy	Stainless steel 304
<b>Shaft Isolation</b>	Nylon (Polyamide 11)	Black Polyolefin	N/A
<b>Sterilization</b>	Steam Sterilization	Ethylene Oxide	Ethylene Oxide
<b>Activation Method</b>	Foot Pedal	Foot Pedal	Footswitch

### Performance Testing Summary:

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

#### Biocompatibility Testing

A biocompatibility assessment was conducted on all skin contacting components. Testing was conducted in accordance with FDA’s guidance entitled “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”. All test results demonstrated acceptable biocompatibility for the patient contacting components.

#### Electromagnetic Compatibility (EMC) and Electrical Safety Testing

The ENTire IRE System complies with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-2, 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 and met all predefined acceptance criteria and supports the safety and effectiveness of the device.

#### Pre-Clinical Animal Safety and Performance Studies

In accordance with FDA’s Guidance, “Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery,” multiple *in vivo* animal studies were conducted to support the safety and performance of the ENTire IRE System. These studies assessed the extent of tissue ablation, healing response, and surrounding tissue effects. The results

demonstrated that the device achieves the intended tissue effects with no evidence of thermal injury beyond the target zone. Based on these findings, the ENTire IRE System is considered safe and effective for ablation of soft tissue and supports substantial equivalence to the predicate device.

#### Summary

The performance testing conducted for the 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:**

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. The ENTire IRE System is as safe, as effective, and performs as well as the predicate devices.