June 3, 2025

Cintron Medical Corporation
William Bowers
Vice President, Product Development
1275 W 124th Ave.
Westminster, Colorado 80234

Re: K250657
Trade/Device Name: gi2000 Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 27, 2025
Received: March 5, 2025

Dear William Bowers:

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,

James H. Jang -S
Digitally signed by James H. Jang -S
Date: 2025.06.03 13:34:52 -04'00'

James Jang, 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

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)*

K250657

Device Name

gi2000 Electrosurgical Generator

Indications for Use *(Describe)*

The gi2000 electrosurgery unit (ESU) is intended to deliver electrosurgical outputs to perform cutting and/or coagulation, in flexible endoscopic applications.

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

Contact Details - 21 CFR 807.92(a)(1)

Cintron Medical Corporation
1275 W 124th Ave.
Westminster CO 80234 United States

Contact Person: Mr. William Bowers
VP of Product Development & Consulting Services
(720) 473-8500
wbowers@cintronmedical.com

Date of Summary: 2025-06-03

Device Name and Classification - 21 CFR 807.92(a)(2)

Common Trade Name:	gi2000 Electrosurgical Generator
Common Name:	Electrosurgical cutting and coagulation device and accessories
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number:	878.440
Classification Product Code:	GEI

Legally Marketed Predicate Device - 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is Listed First)	Product Code
K113265	Gi4000	GEI
K944602	Valleylab Force FX-C	GEI

Device Description Summary - 21 CFR 807.92(a)(4)

The gi2000 is an electrosurgical generator for use in flexible endoscopic clinical settings, employing high-frequency energies to carry out cutting and coagulation of tissue during gastrointestinal surgical procedures. This isolated output electrosurgical unit (ESU) includes all standard features commonly utilized in a broad spectrum of gastrointestinal surgical procedures, encompassing monopolar cutting, monopolar coagulation, and monopolar spray coagulation, along with bipolar coagulation.

The gi2000 consists of the high-frequency electrosurgical unit with control panel and an operating foot switch. The handpiece (electrodes) and dispersive pad (return electrode) are not included with the gi2000. Instead, device labeling lists optional pieces that have been validated with the device.

Intended Use/Indications for Use – 21 CFR 80792(a)(5)

The gi2000 electrosurgery unit (ESU) is intended to deliver electrosurgical outputs to perform cutting and/or coagulation, in flexible endoscopic applications.

Indications for Use Comparison – 21 CFR 807.92(a)(5)

The subject and predicate devices share the same intended use, indications for use, and have similar technical features and output performance.

Technological Comparison – 21 CFR 807.92(a)(6)

The subject and predicate devices share the same fundamental technology: converting electrical energy into high-frequency current for surgical use. Both offer monopolar and bipolar modes at approximately 350 kHz and a maximum power output of 220 Watts. The general and technical characteristics that differ between the predicate and the subject device are differences in software (including the graphical user interface), number of control screens, and power consumption. These differences do not raise concerns about safety and effectiveness based on the results of performance testing.

A reference device is included to support the spray function. The reference device, the Valleylab Force FX-C, cleared under K944602, shares the same regulation number (21 CFR 878.4400) and product code (GEI) as the subject device. Both devices feature mono spray coagulation at approximately 350 kHz and a maximum power output of 110 Watts. Because spray coagulation is a feature of the legally marketed reference device, its performance values show that the subject device's spray coagulation performance values are similar and raise no new safety or effectiveness concerns.

Non-Clinical Tests Summary & Conclusions – 21 CFR 807.92(b)

Performance testing on the gi2000 was completed by three methods. The first method was completed in an ex-vivo study which compared the gi2000 to the predicate device and the reference device. The study compared the spot size and the depth of penetration with comparative modes, power settings and activation times. Results of the study are recorded in 40-0036-11 DS, Predicate Device Comparative Study Report, gi2000.

The second method compared the gi2000 to the predicate device using an assortment of off-the-shelf accessories when applied to a flexible endoscope in an ex-vivo setting. Results of the study are recorded in 40-0036-15, DS, Accessory Compatibility Study Report, gi2000.

The third method compared the gi2000 to the predicate device in an in-vivo setting. The in-vivo test compared the gi2000 to the predicate device comparing the similarities (and variances) on a swine model. The veterinarian surgeon evaluated the performance of each generator using modes and settings as defined in 40-0036-13, DS, In-Vivo Preclinical Test Results, gi2000.

Conclusion

The subject device has the same general intended use and principle of operation as the predicate device. The changes in device hardware and software do not raise different questions of safety or effectiveness. These changes have been verified and validated through nonclinical performance testing. Technological comparison and nonclinical performance testing have demonstrated that the subject device operates as intended and that it is as safe and effective as the predicates for the proposed indications for use.