September 24, 2024

Endocision Technologies Inc.
Anthony Sirgi
Director, Regulatory Affairs and Quality
338 Rue Saint-Antoine Est, Suite 407
Montreal, QC H2Y1A3
Canada

Re: K240776
Trade/Device Name: Celsio Flexible Cryocatheter System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: March 14, 2024
Received: August 30, 2024

Dear Anthony Sirgi:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.09.24 11:44:11 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*

K240776

Device Name

Celsio Flexible Cryocatheter System

Indications for Use *(Describe)*

The Celsio Flexible Cryocatheter System is intended for cryoadhesion applications during interventional procedures such as the removal of tissue, foreign bodies, mucous plugs, blood clots, necrotic tissue, tumors and tissue biopsies, and for palliative devitalization (destruction) of tissue by the application of extreme cold.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Endocision **510(k) Summary: Celsio Flexible Cryocatheter System**

In accordance with the requirements of 21 CFR 807.92 of the Federal Code of Regulations, the following information is a summary of safety and effectiveness for the Celsio Flexible Cryocatheter System.

SUBMITTERS INFORMATION

Submitted by: Endocision Technologies Inc.
338 Rue Saint - Antoine Est, Suite 407
Montreal, Quebec
H2Y1A3, Canada

Contact Person: Anthony Sirgi
Director, Regulatory Affairs and Quality
Tel: 857-529-5014 ext 202

Date Prepared: September 24th, 2024

DEVICE INFORMATION

Registration Number: K240776
Device Trade Name: Celsio Flexible Cryocatheter System
Regulation Name: Cryosurgical Unit and Accessories
Device Class: Class II
Product Code: GEH
Classification Panel: General & Plastic Surgery
Regulation Number: 21 CFR 878.4350

PREDICATE DEVICE

K190651 - ERBECRYO 2 Cryosurgical Unit and Accessories: ERBECRYO 2 cryosurgical unit; Erbe Flexible Cryoprobe

DEVICE DESCRIPTION

The Celsio Flexible Cryocatheter System is a cryosurgical device with a disposable carbon dioxide (CO_2) cartridge that is used with commercially available endoscopes with a minimum working channel diameter of 2mm and maximum working length of 1052 mm, in interventional endoscopic procedures.

The Celsio Flexible Cryocatheter System is comprised of a Flexible Cryocatheter (sterile, single use), a CO_2 Refrigerant Cartridge (non-sterile, single use) and a Refrigerant Dispenser (non-sterile, single use).

The flexible cryocatheter is typically delivered using a compatible endoscope to the target location. Once the refrigerant dispenser is activated, pressurized refrigerant fluid is delivered to the catheter tip where it undergoes expansion to its lower temperature (the Joule-Thomson effect), causing surrounding tissue in contact with the catheter tip to freeze and adhere.

INTENDED USE/INDICATIONS FOR USE

The Celsio Flexible Cryocatheter System is intended for cryoadhesion applications during interventional procedures such as the removal of tissue, foreign bodies, mucous plugs, blood clots, necrotic tissue, tumors and tissue biopsies, and for palliative devitalization (destruction) of tissue by the application of extreme cold.

SUBSTANTIAL EQUIVALENCE COMPARISON

Table 1: Comparison of Celsio Flexible Cryocatheter System (Subject Device) and Erbecryo 2 (Predicate Device)

Characteristics	Subject Device (K240776)	Predicate Device (K190651)
Trade Name	Celsio Flexible Cryocatheter system	ERBECRYO 2 Cryosurgical Unit and Accessories: ERBECRYO 2 cryosurgical unit; Erbe Flexible Cryoprobe
Manufacturer	Endocision Technologies Inc.	Erbe Elektromedizin GmbH
Product Code	GEH	GEH
Regulation	21 CFR 878.4350	21 CFR 878.4350
Device Class	Class II	Class II
Indication for use/Intended Use	The Celsio Flexible Cryocatheter System is intended for cryoadhesion applications during interventional procedures such as the removal of tissue, foreign bodies, mucous plugs, blood clots, necrotic tissue, tumors and tissue	The Erbe Flexible Cryoprobes are intended for palliative devitalization (destruction) of tissue during interventional procedures by the application of extreme cold and cryoadhesion for applications such as the removal of foreign bodies,

	biopsies, and for palliative devitalization (destruction) of tissue by the application of extreme cold.	mucus plugs, blood clots, necrotic tissue, tissue tumors (palliative recanalization) and tissue biopsies.
Target Population	Patients which required removal of foreign body, tissue and palliative destruction of tissue through endoscopic techniques	Patients which required removal of foreign body, tissue and palliative destruction of tissue through endoscopic techniques
Intended Anatomical Site	Endoscopic uses through natural orifice (respiratory tree, GI tract, urethral tract etc.)	Endoscopic uses through natural orifice (respiratory tree, GI tract, urethral tract etc.)
Prescription Use	Yes	Yes
Environment of Use/Usage	Hospital Setting / single-patient use device	Hospital Setting / single-patient use catheter
Cryogenic Gas used	Carbon Dioxide (CO_2)	Carbon Dioxide (CO_2)
Cryogen Source	Disposable CO_2 Cartridge	Refillable CO_2 Cylinder
Provided Sterile	Yes, ethylene oxide (Flexible Cryocatheter and tissue removal tool)	Yes, ethylene oxide (Flexible Cryocatheter and tissue removal tool)
Application of Cryogenic Gas (Cooling activation method)	Handheld Refrigerant Dispenser with a lever	Foot Pedal and Electromechanical console
Dimensions	Outer Diameter: 1.7mm (5 Fr) Working Length: 1200mm	Outer Diameter: 1.7mm (5 Fr) Working Length: 1150mm Umbilical Cord: 2.5m
Connection of Catheter to User Interface	Proprietary Quick-Connect Connector	Proprietary Three-Pronged Connector
Thermodynamic Effect	Joule-Thomson	Joule-Thomson
Safety and Performance Standards	Conformity to current recognized Standards	Conformity to current recognized Standards

The differences are not significant and do not raise additional questions of safety and effectiveness as can be demonstrated by a review of predicate device characteristics, design and development standards, and non-clinical performance testing.

PERFORMANCE DATA

To support the substantial equivalence, performance testing of the subject device was conducted in accordance with the applicable standards and guidance documents to ensure that the subject device performs as intended. Design Verification and Validation testing was performed to evaluate the physical, performance and the safety specifications of the device. Device sterility, shelf life, and biological safety of device materials to the point of use were validated according to FDA recognized consensus standards and guidance documents. Thermal characteristics were tested and measured to evaluate substantial equivalence by assessing the ice ball dimensions, temperature, cooling and thawing rates. Pre-clinical testing (ex-vivo, in-vivo and post mortem) was conducted to evaluate the performance and safety of the subject device. The tests demonstrated that the technological characteristics of the subject device do not raise any new questions of safety or effectiveness. The acceptance criteria have been satisfied for all the tests.

CONCLUSION

The subject device (Celsio Flexible Cryocatheter System K240776) and the predicate device (ERBEcryo2 Cryosurgical unit and accessories, K190651) are both cryosurgical devices intended for cryoadhesion and cryodevitalization. There are only minor technological differences between the two devices. However, the similarities in function, purpose and the performance testing for the subject device assure that it is at least as safe and effective as the legally marketed predicate device.