June 30, 206

Serpex Medical
Krystal Santiago
Regulatory Affairs
3350 Scott Blvd.
Suite 37b
Santa Clara, California 95054

Re: K261068
Trade/Device Name: Maverix Cryo Biopsy Probe (MCB1000);Maverix Cryo Cartridge (CC1000)
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: GEH
Dated: March 31, 2026
Received: April 1, 2026

Dear Krystal Santiago:

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.06.30 15:58:22 -04'00'

Colin K. 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.	K261068

Please provide the device trade name(s).

Maverix Cryo Biopsy Probe (MCB1000);
Maverix Cryo Cartridge (CC1000)

Please provide your Indications for Use below.

The Maverix CryoBiopsy (MCB) Probe is intended for palliative devitalization (destruction) of tissue during interventional procedures by the application of extreme cold and cryo-adhesion for applications such as the removal of foreign bodies, mucus plugs, blood clots, necrotic tissue, tissue tumors (palliative recanalization) and tissue biopsies.

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)

Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
- ☐ Infants (29 days old to < 2 years old)
- ☐ Children (2 years old to < 12 years old)
- ☐ Adolescents (12 years old to < 22 years old)
- ☒ Adults (22 years old and greater)

K261068 510(k) SUMMARY

[AS REQUIRED BY 21 CFR 807.92]

Submitted By	Serpex Medical 3350 Scott Blvd. Suite 37B Santa Clara, CA 95054
Contact Person	Krystal Santiago Regulatory Affairs
Date Prepared	June 26, 2026
Trade/Proprietary Name	Maverix Cryo Biopsy (MCB) Probe (MCB-1000) Maverix Cryo Cartridge (CC-1000)
Common Name	Cryosurgical Unit and Accessories
Classification Name and Code	Cryosurgical Unit and Accessories (21 CFR 878.4350)
Regulatory Class	II
Product Code	GEH
Legally Marketed Predicate Device	ERBECRYO 2 Cryosurgical Unit and Accessories — Erbe Flexible Cryoprobes (K190651), cleared January 7, 2020

Device Description:

The Maverix Cryo Biopsy (MCB) Probe (Model MCB-1000) is a sterile, single-use flexible cryoprobe used for tissue devitalization and tissue or foreign body collection during interventional endoscopic procedures using commercial access instruments, including bronchoscopes and endoscopes.

The MCB Probe system consists of two components supplied in separate packaging: (1) the sterile MCB Probe, comprising a flexible probe with an inline handle and distal working end and biopsy scraper; and (2) the Cryo Cartridge, a non-sterile, single-use disposable nitrous oxide (N2O) refrigerant cartridge housed within a protective cartridge nest. The Cryo Cartridge is inserted into the cartridge housing at the proximal end of the device by a non-sterile surgical assistant and is suspended from an IV pole or equivalent equipment outside the sterile field during use, while the distal working end of the MCB Probe remains within the sterile field.

The MCB Probe operates via the Joule-Thomson effect: pressurized N2O is delivered to the probe tip through a fine orifice, producing rapid cooling via gas expansion. Upon activation, the cooled probe tip causes tissue to freeze and adhere by cryoadhesion. Tissue samples are retrieved by withdrawing the probe while freezing remains engaged. The distal tip incorporates an adjustable sheath providing selectable exposed freeze lengths. A second Cryo Cartridge may be used with a single MCB Probe if the procedure requires more.

Intended Use / Indications for Use:

The Maverix Cryo Biopsy (MCB) Probe is 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, mucus plugs, blood clots, necrotic tissue, tissue tumors (palliative recanalization), and tissue biopsies.

Similarities and Differences of the Subject Device to the Predicate Device (Predicate Comparison/Substantial Equivalence):

Characteristics	K190651 ERBECRYO 2 Cryosurgical Unit and Accessories	K261068 Maverix Cryo Biopsy Probe and Accessories
Manufacturer	Erbe Elektromedizin GmbH (Germany)	Serpex Medical
Device Name	ERBECRYO 2 Cryosurgical Unit and Accessories — Erbe Flexible Cryoprobes	Maverix Cryo Biopsy (MCB) Probe Maverix Cryo Cartridge
Indications for Use (Flexible Cryoprobes)	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, mucus plugs, blood clots, necrotic tissue, tissue tumors (palliative recanalization) and tissue biopsies.	The Maverix Cryo Biopsy (MCB) Probe is 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, mucus plugs, blood clots, necrotic tissue, tissue tumors (palliative recanalization) and tissue biopsies.
Prescription or OTC	Prescription	Same
Principle of Operation	Joule-Thomson effect: expansion of compressed gas produces rapid cooling at probe tip; cryoadhesion of tissue to tip for retrieval or devitalization	Same
Refrigerant Gas	Carbon Dioxide (CO2)	Nitrous Oxide (N2O)
Gas Delivery System	Console with external CO2 cylinder; footswitch activation	Self-contained disposable N2O cartridge; inline handle activation
Probe Type	Flexible cryoprobe	Same
Probe Dimensions (Flexible Cryoprobes)	OD 1.1mm to 2.4mm; Length 1150mm (multiple models)	OD 1.3mm; Length 1150 mm
Tip Configuration	Fixed tip length per probe model	Adjustable via sheath with locking function
Tip Geometry	Blunt tip; exposed during placement through endoscope	Pointed tip; sheathed during placement; exposed at target tissue location
Activation Method	Footswitch connected to console	Inline handle on probe assembly

Characteristics	K190651 ERBECRYO 2 Cryosurgical Unit and Accessories	K261068 Maverix Cryo Biopsy Probe and Accessories
Patient Contact Materials (Flexible Cryoprobes)	Stainless steel, silicone, plastics	Stainless steel, plastics
Contact Duration	Limited duration (<24 hours)	Same
Provided Condition (Flexible Cryoprobes)	Sterile, single-use	Same
Sterilization Method	Ethylene Oxide (EtO) per ISO 11135	Electron Beam (E-beam) Radiation per ISO 11137-1/-2
Gas Canister	Non-Sterile	Same
Shelf Life	Three (3) years	One (1) year
Endoscope Compatibility	Compatible with bronchoscopes and endoscopes	Compatible with bronchoscopes and endoscopes

The technological differences between the MCB Probe and the predicate device do not raise new questions of safety or effectiveness. Performance testing confirms that the MCB Probe is as safe and effective as the predicate device for its intended use.

Summary of Biocompatibility Testing:

Biocompatibility testing was conducted in accordance with ISO 10993-1:2018 and the FDA guidance document "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices — Part 1: Evaluation and Testing within a Risk Management Process" (September 2023). Testing was performed under Good Laboratory Practice (GLP) conditions at an ISO 17025-accredited laboratory.

The MCB Probe is classified as a limited-duration (<24 hours) tissue-contacting device. Five biocompatibility endpoints were evaluated: cytotoxicity, sensitization, irritation/intracutaneous reactivity, acute systemic toxicity, and material-mediated pyrogenicity. All five endpoints passed. The device materials demonstrated biocompatibility for the intended contact type and duration.

Summary of Sterilization Validation:

The MCB Probe is provided sterile to the customer and is a single-use device. Sterilization by electron beam (e-beam) radiation was validated in accordance with ISO 11137-1:2006 and ISO 11137-2:2013. A sterility assurance level (SAL) of 10^{-6} was achieved.

Summary of Shelf-Life Validation:

The shelf life of the packaged MCB Probe was validated on sterilized samples following accelerated aging per ASTM F1980 and transport simulation per ASTM D4169 / ISTA 3A. Sterile barrier integrity was evaluated in accordance with ISO 11607-1:2019 and ISO 11607-2:2019, including seal strength testing per ASTM F88 and bubble leak testing per ASTM F2096. Samples passed all evaluations at the validated shelf life.

Summary of Performance Testing:

Design verification and validation testing was performed to evaluate the physical, performance, and safety specifications of the subject device in accordance with applicable standards, guidance documents, and internal design control procedures per 21 CFR 820.30.

Comparative testing was conducted to determine freezing performance. Comparative ex vivo tissue testing on three different tissues (bovine liver, porcine kidney, and porcine lung) and GLP animal testing in an in vivo porcine model was conducted to compare biopsy weight and in vivo performance, respectively. Mechanical integrity, sheath mechanism function, cartridge and gas delivery performance, sterile barrier and shelf life, and human factors validation were also conducted. Standard testing, biocompatibility testing, and sterilization validation demonstrated that the technological characteristics of the proposed device do not raise any new questions of safety or effectiveness.

Standards Applied:

- ISO 15223-1, Fourth edition 2021-07 — Medical devices: Symbols to be used with information to be supplied by the manufacturer
- ISO 20417, First edition 2021-04 — Medical devices: Information to be supplied by the manufacturer
- ISO 14971, Third edition 2019-12 — Medical devices: Application of risk management to medical devices
- ISO 10993-1, Fifth edition 2018-08 — Biological evaluation of medical devices: Evaluation and testing within a risk management process
- ISO 11137-1, First edition 2006-04 [AMD2:2018] — Sterilization of health care products: Radiation — Part 1: Requirements for development, validation and routine control
- ISO 11137-2, Third edition 2013-06 [AMD1:2022] — Sterilization of health care products: Radiation — Part 2: Establishing the sterilization dose
- ISO 11137-3, Second edition 2017-06 — Sterilization of health care products: Radiation — Part 3: Guidance on dosimetric aspects
- ISO/TS 11137-4, First edition 2020-06 — Sterilization of health care products: Radiation — Part 4: Guidance on process control
- ASTM F1980-21 — Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F640-20 — Standard Test Methods for Determining Radiopacity for Medical Use
- IEC 62366-1, Edition 1.1 2020-06 — Medical devices: Application of usability engineering to medical devices
- ISO 11607-1, Second edition 2019-02 [AMD1:2023] — Packaging for terminally sterilized medical devices: Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2, Second edition 2019-02 — Packaging for terminally sterilized medical devices: Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F1886/F1886M-16 — Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F88/F88M-23 — Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F2096-11 (Reapproved 2019) — Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM D4169-22 — Standard Practice for Performance Testing of Shipping Containers and Systems
- ISTA 3A 2018 — Packaged-Products for Parcel Delivery System Shipment 70 kg or Less

Conclusion:

The Maverix Cryo Biopsy (MCB) Probe has the same intended use as the predicate device (K190651). Differences have been identified between the subject device and predicate. However, testing and analysis demonstrates that none of these differences raises different questions of safety and effectiveness compared to the predicate device. The performance testing demonstrates the subject device is as safe and effective as the predicate device.