August 5, 2024

Erbe Elektromedizin GmbH
Matthias Kollek
Regulatory Affairs Specialist
Waldhoernlestrasse 17
Tuebingen, 72072
Germany

Re: K240932
Trade/Device Name: HybridTherm System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, JOS, GEH
Dated: July 22, 2024
Received: July 22, 2024

Dear Matthias Kollek:

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.

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: 2024.08.05 13:39:20 -04'00'

Long Chen, Ph.D.
Assistant Director
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240932

Device Name
HybridTherm System

Indications for Use *(Describe)*

Indications for Use - VIO 3
The Erbe electrosurgical unit (ESU/Generator) model VIO 3 with instruments and accessories is intended to deliver high frequency (HF) electrical current for the cutting and/or coagulation of tissue, including ablation.

Indications for use - ERBECRYO 2
The ERBECRYO 2 cryosurgical unit and accessories are intended for cryoadhesion, devitalization (destruction) of tissue by the application of extreme cold, and cooling of tissue during radiofrequency ablation.

Indications for use - HybridTherm ablation probes
The HybridTherm probes are intended for ablation and coagulation of soft tissue.
The following probes can also be used for cutting tissue:
HybridTherm monopolar, eTip and HybridTherm bipolar, eTip.

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.

510(k) SUMMARY

Applicant

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Date Prepared

July 22, 2024

Device Information

Trade/Proprietary Name:	HybridTherm System
Common Name:	Electrosurgical cutting and coagulation device and accessories
Classification Name	Electrosurgical cutting and coagulation device and accessories
Regulation Number:	21 CFR 878.4400, 21 CFR 878.4350
Class:	II
Product Code:	GEI & JOS GEH

Legally Marketed Predicate Devices

Primary

EUSRA RF Electrode - K181249

Additional predicate devices

VIVA combo RF System - K163450
Erbe ESU Model VIO 3 - K190823
Single Use Electrosurgical pencil - K192542
ERBECRYO 2 - K190651

Device Description

The HybridTherm system consists of the electrosurgical unit (ESU) Model VIO 3, the cryosurgical unit Model ERBECRYO 2, the HybridTherm ablation probes and accessories.

HybridTherm ablation probes

The HybridTherm probes are a product family consisting of 8 probes to offer the user a range of instruments based upon the physician's preference. There are 4 monopolar and 4 bipolar ablation probes, which differ in the function of the distal end: with and without a monopolar cutting tip (eTip), as well as in their shape (i.e. straight or angulated/curved).
The HybridTherm probes combine high-frequency (HF) technology with cryotechnology. The HF technology is used for cutting (only variants with eTip), coagulation, and ablation of tissue. To reduce tissue desiccation and to increase the ablation zone, the probes are cooled. Cooling also minimizes tissue adhesion to the electrode. The primary function of the cooling is to support the ablation process.

VIO 3

The ESU Model VIO 3 delivers high frequency (HF) electrical current for cutting, coagulation and ablation of tissue. The unit can be mounted/secured to a cart/system carrier or on a ceiling mount. Different Footswitches are available for activating the ESU and as applicable to change modes of the ESU (Remode feature). The ESU Model VIO 3 has several clearly defined cutting, coagulation and ablation modes with different electrical waveforms and electrical parameters that are programmed with defined effect levels. Each effect level corresponds to a defined maximum power output and a voltage limitation. The ESU has a touchscreen monitor that provides the user with an onscreen tutorial as well as settings and operational information. It also provides a small number of physical controls, such as the power switch, instrument sockets and a neutral electrode receptacle.

ERBECRYO 2

The cryosurgical unit Model ERBECRYO 2 is connected to an electrical power source and a carbon dioxide (CO_2) source. Upon activation, the Unit delivers a regulated CO_2 flow to the end of the connected instrument for cooling. The CO_2 returning from the probe to the ERBECRYO 2 exists via the exhaust gas hose. Appropriate gas cylinder adapters are available for the various international gas cylinder connections.

HybridTherm System

The HybridTherm probes are connected to the units (VIO 3 and ERBECRYO 2) via respective plugs. The units are connected to each other via an Erbe Communication Bus (ECB) cable, whereby the user only interacts with the ESU Model VIO 3 (master-slave technology: the cryosurgical unit is controlled via the VIO 3). The ERBECRYO 2 additionally requires a CO_2 gas cylinder. A footswitch is connected to the ESU, with which the activation of the available modes is started. The ESU supplies the HF current which is needed for cutting (only HybridTherm probe variants with eTip), coagulation and ablation of tissue. The ERBECRYO 2 supplies CO_2 gas which is needed for cooling via the Joule-Thomson-effect to support the ablation.

Indications for Use

HybridTherm probes

The HybridTherm probes are intended for ablation and coagulation of soft tissue.
The following probes can also be used for cutting tissue:
HybridTherm monopolar, eTip and HybridTherm bipolar, eTip.

VIO 3

The Erbe electrosurgical unit (ESU/Generator) Model VIO 3 with instruments and accessories is intended to deliver high frequency (HF) electrical current for the cutting and/or coagulation of tissue, including ablation.

ERBECRYO 2

The ERBECRYO 2 cryosurgical unit and accessories are intended for cryoadhesion, devitalization (destruction) of tissue by the application of extreme cold, and cooling of tissue during radiofrequency ablation.

Compared to the predicate device(s), the VIO 3 and the HybridTherm probes have the same intended use. All devices are intended for the application of high frequency (HF) electrical energy in interventional/surgical procedures to thermally effect or destroy tissue.

Compared to the previously cleared cryosurgical unit (ERBECRYO 2), the ERBECRYO 2 that is part of the HybridTherm System has an extended Indications for Use statement (i.e. cooling of tissue during radiofrequency ablation). However, the intended use of both devices is the supply of CO_2 to a connected instrument for cooling via the Joule-Thomson effect. This function is the same for the predicate system. The VIVA Combo RF Generator in combination with the EUSRA RF Electrode uses a peristaltic pump with chilled water to cool the probe/tissue during the application. Therefore, the intended use is essentially the same.

Traditional 510(k) for HybridTherm System

Comparison to predicate devices

VIO 3

Characteristics	Subject Device HybridTherm System (VIO 3)	Primary Predicate Erbe ESU Model VIO 3 with Accessories	Secondary Predicate VIVA Combo RF System	Discussion
Manufacturer	Erbe Elektromedizin GmbH (Germany)	Erbe Elektromedizin GmbH (Germany)	STARmed Co., Ltd.	N/A
510(k)	K240932	K190823	K163450	N/A
Trade/ Proprietary Name	Erbe ESU Model VIO® 3	Erbe ESU Model VIO® 3 with Accessories	VIVA combo RF System	N/A
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical, Cutting & Coagulation & Accessories	Same
Classification Regulation	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	Same
Product Code	GEI	GEI	GEI	Same
Device Class	II	II	II	Same
Indications for Use	The Erbe electrosurgical unit (ESU/Generator) model VIO 3 with instruments and accessories is intended to deliver high frequency (HF) electrical current for the cutting and/or coagulation of tissue, including ablation.	The Erbe Electrosurgical Unit (ESU/Generator) Model VIO® 3 with Accessories is intended to deliver High Frequency (HF) electrical current for the cutting and/or coagulation of tissue.	The VIVA combo RF Ablation System is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.	Same
Prescription or OTC	Prescription	Prescription	Prescription	Same
Dimensions	Width x Height x Depth 415 x 215 x 375 mm 16.3" x 8.5" x 14.8"	Width x Height x Depth 415 x 215 x 375 mm 16.3" x 8.5" x 14.8"	Width x Height x Depth 260 x 115 x 348 mm 10.2” x 4.5” x 13.7”	Same as Primary Predicate

Traditional 510(k) for HybridTherm System

Characteristics	Subject Device HybridTherm System (VIO 3)	Primary Predicate Erbe ESU Model VIO 3 with Accessories	Secondary Predicate VIVA Combo RF System	Discussion
Weight	12 kg/26.7 lbs	12 kg/26.7 lbs	6 kg / 13.2 lbs	Same as Primary Predicate
Technical/ Performance Data	Mains voltage 100 – 120 VAC (±10%) / 220 – 240 VAC (±10%)	Mains voltage 100 – 120 VAC (±10%) / 220 – 240 VAC (±10%)	Mains voltage 100 - 240 V	Same as Primary Predicate
	Mains current max. 6.3A	Mains current max. 6.3A	Not known	Same as Primary Predicate
	Mains frequency 50 Hz / 60 Hz	Mains frequency 50 Hz / 60 Hz	Mains frequency 50 Hz / 60 Hz	Same
	Frequency 350 kHz	Frequency 350 kHz	Frequency 480 kHz	Same as Primary Predicate
	Maximum Power Output 400 watts	Maximum Power Output 400 watts	Maximum Power Output 200 watts	Same as Primary Predicate
WiFi connection	Available (deactivated by default, no HF-activation possible if WiFi is enabled)	Available (deactivated by default, no HF-activation possible if WiFi is enabled)	Not available	Same as Primary Predicate
Output Modules/ Receptacles	4 HF instrument sockets 1 Neutral electrode socket 2 Footswitch sockets	4 HF instrument sockets 1 Neutral electrode socket 2 Footswitch sockets	1 HF Cable socket 2 Neutral electrode sockets 2 Footswitch sockets	Same as Primary Predicate
Software Version	V1.1.x	V2.0.x	1.10	Different Software Version
Accessories	One- and two- pedal Foot switches	One- and two- pedal Foot switches	One- and two- pedal Foot switches	Same
	Connection cables	Connection cables	Connection cables	Same
	Neutral Electrodes	Neutral Electrodes	Neutral Electrodes	Same
	VIO-Cart, System Carrier compact and System Carrier compact plus	VIO-Cart	N/A	New system Carriers

Traditional 510(k) for HybridTherm System

Characteristics	Subject Device HybridTherm System (VIO 3)	Primary Predicate Erbe ESU Model VIO 3 with Accessories	Secondary Predicate VIVA Combo RF System	Discussion
	N/A	N/A	Peristaltic Pump	Secondary predicate device uses a peristaltic pump for cooling of the connected ablation electrode.
Condition provided / Use condition	Non-sterile / reusable	Non-sterile / reusable	Non-sterile / reusable	Same

HybridTherm Probes

Characteristics	Subject Device HybridTherm probes	Primary Predicate EUSRA RF Electrode	Secondary Predicate Single Use Electrosurgical pencil	Discussion
510(k) Number	K240932	K181249	K192542	N/A
Trade/Proprietary Name	HybridTherm Probes	EUSRA RF Electrode	Single Use Electrosurgical pencil with non-coated and non-stick electrode (Non-sterile and sterile)	N/A
Manufacturer	Erbe Elektromedizin GmbH	STARmed Co., Ltd.	Modern Medical Equipment Manufacturing, LTD.	N/A
Classification Name	Electrosurgical Cutting and Coagulation Device and Accessories	Electrosurgical Cutting and Coagulation Device and Accessories	Electrosurgical Cutting and Coagulation Device and Accessories	Same
Classification Panel	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery	Same
Classification Regulation	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	Same
Product Code	GEI, JOS	GEI, JOS	GEI	Same

Traditional 510(k) for HybridTherm System

Characteristics		Subject Device HybridTherm probes	Primary Predicate EUSRA RF Electrode	Secondary Predicate Single Use Electrosurgical pencil	Discussion
Device Class		Class II	Class II	Class II	Same
Indications for Use		The HybridTherm probes are intended for ablation and coagulation of soft tissue. The following probes can also be used for cutting tissue: HybridTherm monopolar, eTip and HybridTherm bipolar, eTip.	The EUSRA RF Electrode is indicated for coagulation and ablation of soft tissue when used in conjunction with compatible radio frequency generator.	The devices are used to cut and coagulate soft tissue by means of high frequency electrical current during an electrosurgical procedure.	Same
Energy Used		HF electrical current	HF electrical current	HF electrical current	Same
Operating Principle		Monopolar and Bipolar	Monopolar	Monopolar	Similar
Cooling Technology		CO_2 (Joule-Thompson Effect)	Cooled Water	N/A	Similar
Physical Specifications	**Tip Length**	Monopolar variants: 9.05mm (active electrode) Bipolar variants: 2x 9,05mm + 1,2mm Isolator = 19,3mm	5, 7, 10, 15, 20mm	69mm, 102mm, 152mm (blade electrode)	Within dimensions of primary predicate
	Tip Diameters	1.9mm	19 Gauge (1.06mm)	2.36mm	Within dimensions of primary and secondary predicate
	Flexible Shaft	1250mm	1393mm	N/A	Similar to primary predicate
Patient Contacting Materials		Stainless Steel, Gold, Plastics	Stainless Steel, Plastics	Plastics, Stainless steel, Teflon one coat	Similar
Condition provided / Use condition		Sterile, single use	Sterile, single use	Sterile, single use	Same
Sterilization method		EO Sterilization	EO Sterilization	EO Sterilization	Same
Extensible Tip Length		Not extensible	Extensible Tip Length	Not extensible	Same as secondary predicate

Traditional 510(k) for HybridTherm System

ERBECRYO 2

Characteristics	Subject Device HybridTherm System (ERBECRYO 2)	Predicate Device ERBECRYO 2 Cryosurgical Unit and Accessories	Discussion
510(k) Number	K240932	K190651	Different
Model Name	ERBECRYO® 2 Cryosurgical Unit and Accessories	ERBECRYO® 2 Cryosurgical Unit and Accessories	Same
Manufacturer	Erbe Elektromedizin GmbH	Erbe Elektromedizin GmbH	Same
Common Name	Cryosurgical Unit and Accessories	Cryosurgical Unit and Accessories	Same
Classification Regulation	21 CFR 878.4350	21 CFR 878.4350	Same
Product Code	GEH	GEH	Same
Device Class	II	II	Same
Indications for Use	The ERBECRYO 2 cryosurgical unit and accessories are intended for cryoadhesion, devitalization (destruction) of tissue by the application of extreme cold, and cooling of tissue during radiofrequency ablation.	The ERBECRYO® 2 cryosurgical unit and accessories are intended for cryoadhesion and devitalization (destruction) of tissue by the application of extreme cold.	Equivalent, extended Indications for Use fall within the intended use
Intended Use	Supply of CO_2 to a connected instrument for cooling via the Joule-Thompson effect.	Supply of CO_2 to a connected instrument for cooling via the Joule-Thompson effect.	Same
Prescription or OTC	Prescription	Prescription	Same
Materials	Metal sheet, aluminum, copper pipes, plastics and wiring, electronic components	Metal sheet, aluminum, copper pipes, plastics and wiring, electronic components	Same
Type, Dimensional, and Physical Attributes as well as Performance and Other Specifications			
Dimensions of Unit	16.1”x5.1”x14.6” 410x130x370mm)	16.1”x5.1”x14.6” 410x130x370mm)	Same
Weight of Unit	14.8lbs (6.7kg)	14.8lbs (6.7kg)	Same

Traditional 510(k) for HybridTherm System

Characteristics	Subject Device HybridTherm System (ERBECRYO 2)	Predicate Device ERBECRYO 2 Cryosurgical Unit and Accessories	Discussion
Technical Data of Unit	Rated supply voltage: 100 - 240V (±10%)	Rated supply voltage: 100 - 240V (±10%)	Same
	Rated supply frequency: 50 - 60Hz	Rated supply frequency: 50 - 60Hz	Same
	Line current: 0.4 - 0.8A	Line current: 0.4 - 0.8A	Same
Software Version	2.0.0	1.0.3	Different
Remote control by VIO 3	Yes	No	Different
Performance Data of Unit	No. of effect levels: 1 - 5 (depending on instrument)	No. of effect levels: 1 - 5 (depending on instrument)	Same
	Activation: via footswitch	Activation: via footswitch	Same
	Cooling gas used: CO_2	Cooling gas used: CO_2	Same
	Input Pressure: 653 - 943psi (45 - 65bar)	Input Pressure: 653 - 943psi (45 - 65bar)	Same
Other Compatible Equipment	ERBECRYO 2 Cart, VIO Cart, cable, gas hoses, gas bottle adapter	ERBECRYO 2 Cart, VIO Cart, cable, gas hoses, gas bottle adapter	Same
Provided Condition	Non-sterile, reusable	Non-sterile, reusable	Same

Comparison of Technological Characteristics

Differences of the ESU Model VIO 3 compared to the previously cleared device is an updated software mainly to introduce new modes for cutting, coagulation and ablation of tissue, remote control of the cryosurgical unit ERBECRYO 2 and operation/control of the HybridTherm probes.
Compared to the primary predicate device EUSRA RF Electrode the HybridTherm probes have an additional bipolar variant, a monopolar cutting tip (only variants with eTip) and a lateral and distal coagulation feature. The HybridTherm probes are cooled via CO_2 compared to cooling via chilled water which is employed by the predicate probes. In addition, the HybridTherm probes have different materials and different physical specifications which are, however, within the specifications of the respective predicate devices.
Difference of the ERBECRYO 2 compared to the predicate device is an updated software for remote control via the VIO 3 and operation/control of the HybridTherm probes.

The subject device system and the predicate device(s) use the same energy (HF electrical current) and principles of operation. Both the monopolar and bipolar technology are established and routinely adopted in interventional procedures for many years. Compared to the monopolar variant, the bipolar variant does not raise different issues of safety and effectiveness. The cooling technology of the subject device by means of CO_2 is the same compared to the previously cleared ERBECRYO 2. Although the predicate system uses a different cooling technology (chilled water), the purpose of the cooling is the same and the cooling is only used to support the ablation process.
Side-by-side tissue testing against the respective predicate device(s) shows that the performance (i.e. cutting, coagulation and ablation) is as good as the performance of the predicate device(s). The non-clinical testing described below shows that the different technological characteristics do not negatively affect the safety and effectiveness of the subject device.

Non-clinical performance testing

Verification/validation activities from non-clinical testing as described below demonstrate that the differences do not raise any new or different issues of safety or effectiveness of the subject device compared to the predicate devices.

Functional testing and design controls to verify both safety and performance of the subject device was performed in compliance with 21 CFR 820.30 to ensure that the subject device performs as intended and meets design specifications.

Side-by-side tissue testing was performed in compliance with FDA Guidance “Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery”, to validate the cutting, coagulation and ablation performance compared to the predicate device(s).

Electromagnetic compatibility (EMC) was tested in compliance with IEC 60601-1-2 and FDA Guidance “Electromagnetic Compatibility (EMC) of Medical Devices”.

Electrical safety of the subject device was tested in compliance with, IEC 60601-1; IEC 60601-2-2 and IEC 60601-2-18, as applicable.

Software verification and documentation for cybersecurity was provided in compliance with IEC 62304 and FDA Guidance Documents “Content of Premarket Submissions for Device Software Functions” and “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”.

Biocompatibility testing was performed in compliance with ISO 10993-1 and FDA Guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" to demonstrate biocompatibility of the materials with tissue contact.

Sterilization validation was performed in compliance with ISO 11135 and documentation was provided according to FDA Guidance “Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile” showing an SAL of 10^{-6}. EO residual testing and limits comply with ISO 10993-7.

Packaging and shelf-life validation was performed in compliance with ISO 11607-1, ISO 11607-2 and accelerated aged devices (ASTM F 1980).

Conclusion

The subject device has the same intended use, the same fundamental design, substantially equivalent performance characteristics, and the same energy source as the predicate devices. The subject device was tested as described above and the minor differences in technological characteristics were assessed with regards to safety and effectiveness. Taken together, the subject device does not raise new or different questions of safety and effectiveness, and the subject device is substantially equivalent to the predicate devices for the requested indications for use.