June 15, 2023

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

Re: K231023
Trade/Device Name: ERBEJET® 2 System
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet Lavage
Regulatory Class: Class II
Product Code: FQH, GEI
Dated: April 4, 2023
Received: April 11, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.06.15 13:05:12 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231023

Device Name
ERBEJET® 2 System

Indications for Use *(Describe)*

Indications for Use - Hydrosurgical unit:
The Erbe hydrosurgical unit ERBEJET 2 with instruments and accessories is intended to pressurize a medium to perform needle-free injection and tissue-selective hydrodissection of soft tissue. The Erbe hydrosurgical unit ERBEJET 2 with instruments and accessories is used in endoscopic and surgical procedures.

Indications for Use - Applicators and ERBEJET probe:
20150-220: The ERBEJET probe is intended for dissection (tissue-selective hydrodissection) including separation of soft tissue in endoscopic interventions. The ERBEJET probe can be used for needle-free injection including lifting of mucosal lesions by injection into the submucosa.

20150-225: The applicator is intended for dissection (tissue-selective hydrodissection) including separation of soft tissue in open surgery.

20150-226: The applicator is intended for dissection (tissue-selective hydrodissection) including separation of soft tissue in minimal invasive surgery. The applicator can be used for needle-free injection including lifting of mucosal lesions by injection into the submucosa.

20150-230, 20150-231, 20150-239: The applicators with suction are intended for dissection (tissue-selective hydrodissection) including separation of soft tissue in open surgery. The applicators with suction can be used as well for suction when connected to an external suction module e.g. Erbe ESM 2.

20150-238: The applicator with suction is intended for dissection (tissue-selective hydrodissection) including separation of soft tissue in minimal invasive surgery. The applicator with suction can be used as well for suction when connected to an external suction module e.g. Erbe ESM 2.

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
[AS REQUIRED BY 21 CFR 807.92(C)]

Applicant

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Germany
Tel: 0049-7071-755-0
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Contact Person

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Regulatory Affairs Specialist
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Date Prepared

June 6, 2023

Device Information

Trade/Proprietary Name:	ERBEJET® 2 System
Common Name:	Hydrosurgical Unit and Accessories
Classification Name	Jet lavage
Regulation Number:	21 CFR 880.5475
Class:	II
Product Code:	FQH

Legally Marketed Predicate Devices

ERBE ERBEJET 2 System - K072404 and
ERBE Water Jet Model ERBEJET® 2 System with HybridAPC Probe - K143306

Device Description

The ERBEJET® 2 System includes the Hydrosurgical unit model ERBEJET® 2, the pump cartridge plus, instruments (applicators and ERBEJET probe), an optional suction model ESM 2 with accessories and a one- or two-pedal footswitch. Together these components form the ERBEJET® 2 System. The system provides an adjustable high-pressure water jet (pressurized normal saline solution) intended for tissue-selective hydrodissection and needle-free injection in endoscopic and/or surgical interventions. The ERBEJET® 2 unit together with its accessories is an active invasive surgical system. The sterile normal saline solution is the "medium" which is projected under pressure through a nozzle of the connected instrument to achieve the desired tissue effect.

Hydrosurgical Unit

The ERBEJET® 2 Hydrosurgical Unit is a standalone Unit that can be mounted / secured to a cart. It has a monochromatic display (blue/white) that provides the user with settings and operational information. The display is surrounded by buttons allowing the user to control the unit (e.g., set the effect, select a program). In order to pressurize and deliver the medium to a connected Applicator, a pump cartridge (attached to the medium) must be connected to the ERBEJET 2. Activation of the Unit and subsequent delivery of the medium is possible with a connected footswitch. The pressure ranges from 1 to 80 bar (+/-20%) (14.5 - 1160.3psi (+/-20%)) which corresponds to a volume flow of 3.5 – 55 ml/min (± 10% or ± 1 ml, depending on which value is larger).

Applicators and ERBEJET probe

The applicators and ERBEJET probe are sterile, single-use instruments which are available in various length and diameters as well as with or without an additional suction line.

Accessories

Pump cartridge plus

The single use sterile pump cartridge is inserted into the ERBEJET® 2 unit. It has a chamber with two pistons and is the conduit for the medium which is connected to the cartridge via luer lock to be pressurized. The pressure is mechanically provided by the ERBEJET® 2 unit by engaging the pistons of the pump cartridge.

Footswitch

A one-pedal and two-pedal footswitch have been designed for the ERBEJET® 2. The footswitches are used to activate the Unit.

Suction module and accessories

The optional suction module ESM 2 can be integrated into the ERBEJET 2 System. Various accessories (i.e. filter, suction hose, etc.) connect the ESM 2 to a suction container and to the applicator to aspirate fluids from the surgical site.

Other accessories

Accessories that may be used for the mounting of the unit.

Indications for Use

ERBEJET® 2

The Erbe hydrosurgical unit ERBEJET 2 with instruments and accessories is intended to pressurize a medium to perform needle-free injection and tissue-selective hydrodissection of soft tissue. The Erbe hydrosurgical unit ERBEJET 2 with instruments and accessories is used in endoscopic and surgical procedures.

Applicators and ERBEJET probe

20150-220: The ERBEJET probe is intended for dissection (tissue-selective hydrodissection) including separation of soft tissue in endoscopic interventions. The ERBEJET probe can be used for needle-free injection including lifting of mucosal lesions by injection into the submucosa.

20150-225: The applicator is intended for dissection (tissue-selective hydrodissection) including separation of soft tissue in open surgery.

20150-226: The applicator is intended for dissection (tissue-selective hydrodissection) including separation of soft tissue in minimal invasive surgery. The applicator can be used for needle-free injection including lifting of mucosal lesions by injection into the submucosa.

20150-230, 20150-231, 20150-239: The applicators with suction are intended for dissection (tissue-selective hydrodissection) including separation of soft tissue in open surgery. The applicators with suction can be used as well for suction when connected to an external suction module e.g. Erbe ESM 2.

20150-238: The applicator with suction is intended for dissection (tissue-selective hydrodissection) including separation of soft tissue in minimal invasive surgery. The applicator with suction can be used as well for suction when connected to an external suction module e.g. Erbe ESM 2.

Compared to the legally marketed predicate devices, the subject device has a reworded indications for use statement. In general, Erbe would like to have a more encompassing indications for use (intended use) for the unit, and have more specifics as to applications in the instrument's indications for use (intended use). Erbe changed the term injection to needle-free injection for clarification since the instruments don´t have a needle. The phrase dissection of tissue was changed to tissue-selective hydrodissection since this is the commonly used clinical term which is used by physicians and supported by peer-reviewed literature. Furthermore, the term "cutting" has been omitted for clarification purposes since dissection/hydrodissection is a more accurate term for water jet application (Note: From a clinicians view point, "cutting" is a term in electrosurgery that is associated with the delivery of monopolar or bipolar energy or a term in general surgery of a mechanical nature, e.g. scalpel). Additionally, the indications for use of the associated instruments (i.e. applicators and ERBEJET probe) will then provide further specifics for optimal use in a clinical setting in accordance with the proposed intended use of the unit. Therefore, the phrases "lifting mucosal lesions by injection into the submucosa" which is associated with the function "needle-free injection" and "separation of soft tissue"

which is associated with the function “tissue-selective hydrodissection” are additionally being used for the indications for use statement of the applicators and ERBEJET probe as applicable. Taken together, the indications for use statement was reworded for clarity in order to better describe the actual function without changing the original meaning. The intended use is substantially equivalent compared the predicate device.

Comparison of Technological Characteristics with the Predicate Device

Compared to the legally marketed predicate devices the subject device has additional applicators and the ERBEJET probe. The additional instruments have partially different materials and dimensions. However, the energy source and technological principle is the same. Since the ERBEJET® 2 system is a volume-controlled system, the flow rate is always the same and independent of the instruments design. The only performance parameter that is influenced by the instrument design is the dynamic pressure which depends on the nozzle geometry. Since all proposed applicators and the ERBEJET probe have the same nozzle geometry as the predicate devices, the generated dynamic pressure, and hence, the performance is also the same.

Another change is related to the pump cartridge. Compared to the legally marketed predicate device, the subject device has a new pump cartridge with optimized design. The design modifications were made to improve the insertion behavior into the unit, to enable the change of instruments during surgery and to improve the priming process. Furthermore, the proposed pump cartridge also has slightly different materials compared to the predicate pump cartridge. However, bench testing showed that the performance specifications (i.e. delivery of the medium) remain unchanged and that the new pump cartridge is as safe and effective as the legally marketed pump cartridge, and does not raise different questions of safety and effectiveness.

Non-clinical performance testing

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

Electrical safety and electromagnetic compatibility testing were verified by means of IEC 60601-1 and IEC 60601-1-2 in combination with FDA Guidance “Electromagnetic Compatibility (EMC) of Medical Devices”, respectively.

Functional testing and design controls to verify adequate 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.

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 exclude a negative impact as

a result of the material changes.

Sterilization validation was performed in compliance with ISO 11135 and documentation was provided according 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 are in compliance with ISO 10993-7.

Packaging and shelf life validation was performed in compliance with ISO 11607-1 and real-time aged devices. Functional testing was also performed on real-time aged devices.

Software verification and validation was performed in compliance with IEC 62304 and documentation provided according FDA Guidance “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”.

Conclusion

The subject device has the same intended use, the same fundamental design, the same performance characteristics and energy source as the predicate device. 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 device.