August 31, 2023

Walz Elektronik GmbH
Bernd Vollmer
CEO
Walddorfer Strasse 40
Rohrdorf, Baden-Wuertemberg 72229
Germany

Re: K230488
Trade/Device Name: EL27-Compact
Regulation Number: 21 CFR§ 876.4480
Regulation Name: Electrohydraulic Lithotriptor
Regulatory Class: II
Product Code: FFK
Dated: August 3, 2023
Received: August 3, 2023

Dear Bernd Vollmer:

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 J. Antonino -S

Mark J. Antonino, M.S.
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)*
K230488

Device Name
EL27-Compact

Indications for Use *(Describe)*
The EL27-Compact is a device to be used together with EHL-probes from Walz Elektronik GmbH for disintegration of concernments in the upper and lower urinary tract and in gastroenterology, particularly in the bile duct.

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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General

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Date Prepared:

21.02.2023

Predicate Devices

Predicate Device		510(k) No.
AUTOLITH TOUCH		K130368
AUTOLITH URO-TOUCH		K130368
1.9 FRENCH LITHOTRIPTER ELECTRODE, MODIFICATION		K914514
3 FRENCH LITHOTRIPTER ELECTRODE, MODIFICATION		K914515
9 FRENCH LITHOTRIPTER ELECTRODE, MODIFICATION		K914516
1.9 FRENCH LITHOTRIPTER ELECTRODE, MODIFICATION		K913955

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Device Description

The EL27-Compact is a device, designed to be used with Walz Elektronik GmbH disposable EHL-Probes for the fragmentation of concrements in the gastroenterology and urology.
A physician inserts and pushes the disposable EHL probe through the working channel of an endoscope and places the tip of the probe in front of the stone surrounded with saline solution. With pressing the footswitch, the device provides electric pulse energy in form of a high-voltage pulse. This pulse generates high pressure shockwaves that fragment hard stones.
The EL27-Compact is a table-top device and consists of the generator itself, the power cord, the footswitch, a probe cable for connection between the probes and the device and the EHL-probes.

Regulation Name:	Lithotripter, Electro-Hydraulic
Regulation Number:	21 CFR. 876.4480
Regulatory Class:	Class II
Product Codes: Review	FFK
Panel:	Gastroenterology/Urology
Trade Name:	EL27-Compact
Generic/Common Name:	Lithotripter

Indications for use

The EL27-Compact is a device to be used together with EHL-probes from Walz Elektronik GmbH for disintegration of concernments in the upper and lower urinary tract and in gastroenterology, particularly in the bile duct.

Comparison of Technological Characteristics

Generator

- Both devices, the predicate and the subject of this 510(k) submission, are used in the field of urology and gastroenterology for fragmentation of concrements.
- Both devices are table-top units that connect over a probe connecting cable to a disposable probe that, is used in the working channel of an endoscope. The physician inserts and pushes the disposable EHL probe through the working channel of a compatible endoscope and places the tip of the probe in front of the stone surrounded with saline solution (0,9% isotonic saline solution). With pressing the footswitch, the device provides electric pulse energy in form of a high-voltage pulse. This pulse generates high pressure shockwaves that fragment hard stones.
- Both devices have a selection of 3 intensities (Low, Medium, High)
- Both devices' outputs are controlled over a footswitch
- Both devices are used in hospital environment
- Both devices are made of commonly used materials for building electronic devices

Disposable EHL Probes

- Both probe types have a proprietary connection to the generator
- Both probe types are sterile and for single-use
- Both probe types are made of similar materials like epoxy, stainless steel, copper, Polyimid, Polyvinylidenfluorid or Polyolefin
- Both probe types have the tip of the probe as the patient contacting part
- Both probe types are sterilized with ethylene oxide

Summary of Performance Testing

The following performance testing was conducted in support of the substantial equivalence determination.

Biocompatibility Evaluation

The EL27-Compact does not contain components that come directly or indirectly in patient contact. Biocompatibility testing according to ISO 10993-1 for these components is not required. Biocompatibility evaluation of the patient contacting EHL-Probes were successfully conducted previously according to ISO 10993-1 Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing. There have been no changes that have impacted the established biocompatibility.

1. Biological Safety Evaluation of EHL Probes
2. In vitro Cytotoxicity testing
3. Testing for contact allergens
4. Testing for tissue compatibility

Bench Testing

These comprehensive validation bench tests support equivalence to the predicate device. Testing confirmed that comparable effects could be achieved for applicable modes of operation.

For the EHL-Probe, the following tests were performed:

- Visual inspection of the appearance of the probes
- Measuring the dimensions to check if tolerances are okay
- Insertion (not P4,5/3000/f) of probes into an Endoscope
- Measuring the shockwaves
- Measuring withdrawing force of the tip of the probes
- Measuring the electrode consumption.

For the EL27, the following test was performed:

The Test performed was to set up the 3 devices and connect them to 3Fr. Probes. Choosing the different intensities on the devices, pulses have been emitted on a piece of plasterboard. The distance of the probe to the plasterboard have been kept the same overall tests. The resulting holes in the plasterboard, which vary in depth caused by the chosen intensity, can be compared to another.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC performance testing have been confirmed to be in compliance with the relevant requirements as noted below.

- IEC60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance
- IEC 60601-1:2005+AMD1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Software Verification and Validation Testing

Software testing has been performed and documented accordingly to the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Substantial Equivalence

The predicate device is composed of a generator, a probe cable, a foot switch and a power cable. The indications for use, principles of operation, fundamental technology of the generator are identical to the predicate device. It has full compatibility with the existing device and so that users can select from the entire instrument line-up. The indicated patient population and procedures are also identical to the predicate devices. However, functions and principles of operation are identical to the predicate device.

Conclusion

In summary, the EHL-Probes, the EL27-Compact and its accessories are at least substantially equivalent to the predicate devices and present no new questions of safety or effectiveness.