May 28, 2025

Guangzhou Potent Medical Equipment Joint-Stock Co., Ltd.
Zhengzhou Li
General Manager
Rm 5002-5003, A01 Bldg, Ping'an Tech. Guigu Industrial Park
No.74 Chuangyu Road, Ningxi Street, Zengcheng District
Guangzhou, Guangdong 510000
China

Re: K242888
Trade/Device Name: Electrohydraulic Lithotriptor (TCS-B3-II)
Regulation Number: 21 CFR 876.4480
Regulation Name: Electrohydraulic lithotriptor
Regulatory Class: Class II
Product Code: FFK

Dear Zhengzhou Li:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 21, 2025. Specifically, FDA is updating this SE letter to correct the official correspondent as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Anthony C. Lee, OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices, (240) 402-5935, Anthony.Lee1@fda.hhs.gov.

Sincerely,

Anthony Lee -S

Anthony C. Lee, Ph.D., M.B.A.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

March 21, 2025

Guangzhou Potent Medical Equipment Joint-Stock Co., Ltd.
Zhengzhou Li
General Manager
Room 208, Building C, No. 3,
Juquan Road, Huangpu District
Guangzhou, Guangdong 510000
China

Re: K242888
Trade/Device Name: Electrohydraulic Lithotriptor (TCS-B3-II)
Regulation Number: 21 CFR 876.4480
Regulation Name: Electrohydraulic Lithotriptor
Regulatory Class: Class II
Product Code: FFK
Dated: February 17, 2025
Received: February 21, 2025

Dear Zhengzhou Li:

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,

Anthony Lee -S

Anthony Lee, Ph.D., M.B.A.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology 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)*

K242888

Device Name

Electrohydraulic Lithotriptor (TCS-B3-II)

Indications for Use *(Describe)*

The Electrohydraulic Lithotriptor is intended to be used with Potent Medical disposable electrohydraulic lithotripsy (EHL) probes for disintegration of concernments 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.

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

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510(k) Summary

510(k) Number: K242888

Date Prepared: March 10, 2025

Device Name: Electrohydraulic Lithotriptor (TCS-B3-II)

I. Submitter Information

Submitter: Guangzhou Potent Medical Equipment Joint-Stock Co. Ltd.

Address: Room 208, Building C, No. 3, Juquan Road, Huangpu District, Guangzhou, Guangdong Province, China.

Manufacture Address: Room 5002-5003, A01 Building, Ping'an Technology Guigu Industrial Park, No.74 Chuangyu Road, Ningxi Street, Zengcheng District, Guangzhou, Guangdong Province, China.

Contact Person: Zhengzhou Li, General Manager

Room 5002-5003, A01 Building, Ping'an Technology Guigu Industrial Park, No.74 Chuangyu Road, Ningxi Street, Zengcheng District, Guangzhou, Guangdong Province, China.

E-Mail Address: potent_medical_public@potent-medical.com

Phone: +86 -20-37396970

Fax: +86 -20-37376979

II. Device Information

- Regulation Name: Electrohydraulic lithotriptor
- Regulation Number:21 CFR. 876.4480
- Regulatory Class: Class II
- Product Codes: FFK
- Device Panel: Gastroenterology/Urology
- Trade Name: Electrohydraulic Lithotriptor (TCS-B3-II)
- Generic/Common Name: Lithotripter
- Model: TCS-B3-II

III.Predicate Device

- Predicate Device 510(k) Number: K230488
- Trade Name: EL27-Compact; Sterile EHL-Probes
- Regulation Name: Electrohydraulic lithotriptor
- Regulation Number:21 CFR. 876.4480

- Regulatory Class: Class II
- Product Codes: FFK
- Device Panel: Gastroenterology/Urology
- Manufacturer: Walz Elektronik GmbH

IV. Device Description

The EHL is a compact, table-top medical device designed for the fragmentation of biliary calculi. It operates by generating high-voltage electric pulses, which are transmitted through a compatible disposable EHL probe (sold separately) that is inserted into the biliary tract via an endoscope. The device features two operational modes: single pulse and continuous pulse. These electric pulses create hydraulic shock waves in a saline medium, causing fragmentation of biliary stones into smaller pieces that can either be naturally passed or removed endoscopically.

Components of the EHL:

- Generator : Generates high-voltage electric pulses for stone fragmentation.
- Foot switch: Controls the delivery of electric pulses to the probe.
- Power Supply Cable: Provides electrical connection to the generator.

Note: The EHL system does not include disposable EHL probes. It is designed to be used with Potent Medical's compatible disposable EHL probes, which are purchased separately and used during endoscopic procedures.

V. Indications for use

The Electrohydraulic Lithotriptor is intended to be used with Potent Medical disposable electrohydraulic lithotripsy (EHL) probes for disintegration of concernments in the bile duct.

VI. Comparison of Technological Characteristics:

The EHL system and the predicate device, EL27-Compact (K230488), share the same intended use and core operating principles. Both devices generate high-voltage pulses that produce hydraulic shock waves to fragment biliary stones. Both systems rely on compatible disposable EHL probes for their operation.

The table below provides a side-by-side comparison of the modified device to the predicate device.

Technological Similarities:

- Both systems generate high-voltage electric pulses to produce hydraulic shock waves.
- Both are table-top units designed to be used in conjunction with endoscopes and disposable EHL probes.
- Both devices are controlled via a foot switch, allowing the user to regulate pulse delivery during the procedure.
- Both systems offer adjustable power settings to accommodate different types of biliary stones.
- Both system provide equivalent functionality for single pulse and continuous pulse modes.

Technological Differences:

- The EHL system features an advanced touch screen interface, which provides a more user-friendly experience than the simpler interface of the EL27-Compact.
- The EHL system is lighter and more portable than the predicate device, making it easier to transport between different clinical environments.

These technological differences do not affect the safety or effectiveness of the device and do not raise new questions of safety or effectiveness.

VII. Performance Data

The EHL system underwent a series of rigorous performance and safety tests to ensure compliance with applicable regulatory standards.

- Bench Testing
  - Stone Fragmentation Test： Validated the system's ability to generate consistent high-voltage pulses and hydraulic shock waves capable of fragmenting biliary stones. Power output was tested across all settings (low, medium, high), ensuring reliable and safe pulse delivery.
  - Shockwave Pressure Attenuation Test: Comparative analysis of maximum shock wave propagation distance and pressure attenuation profile between TCS-B3-II and predicate device EL27-Compact (K230488). The system was tested for compliance with IEC 61846.
  - Acoustic Characterization Test: Comparative testing of key electrohydraulic shock wave parameters between TCS-B3-II and predicate device. The system was tested for compliance with IEC 61846.

- Electrical Safety and Electromagnetic Compatibility (EMC) Testing:

  The system was tested for compliance with IEC 60601-1 (General Requirements for Basic Safety) and IEC 60601-1-2 (EMC Requirements). The tests confirmed that the device meets the necessary safety and electromagnetic compatibility standards for medical electrical equipment.

- Software Verification and Validation:

The software that controls the EHL system underwent thorough verification and validation testing in accordance with FDA’s guidance for medical device software. All key functionalities, including foot switch operation, pulse regulation, and user interface interactions, were tested for accuracy and reliability. The software for this device was considered as basic documentation level, since failure or latent flaw of the device software function(s) would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures.

The Electrohydraulic Lithotriptor was tested with its compatible EHL Probe in the relevant test items and is provided “For prescription use only.”

VIII. Conclusion

Based on the nonclinical testing results, device comparisons, and functional similarities, the EHL is substantially equivalent to the predicate device, EL27-Compact (K230488). Both devices share the same intended use, technological characteristics, and performance capabilities. The differences, such as the enhanced user interface and improved portability, do not introduce any new questions of safety or effectiveness. Therefore, the EHL is as safe and effective as the predicate device and is suitable for use in its intended clinical applications.