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: K243032
Trade/Device Name: EHL Probe (SCDG-AS); EHL Probe (SCDG-BS); EHL Probe (SCDG-CS)
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 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: K243032
Trade/Device Name: EHL Probe (SCDG-AS); EHL Probe (SCDG-BS); EHL Probe (SCDG-CS)
Regulation Number: 21 CFR 876.4480
Regulation Name: Electrohydraulic Lithotriptor
Regulatory Class: Class II
Product Code: FFK
Dated: February 24, 2025
Received: February 25, 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.

510(k) Number *(if known)*
K243032

Device Name
EHL probe (SCDG-AS); EHL probe (SCDG-BS); EHL probe (SCDG-CS)

Indications for Use *(Describe)*
The EHL probe is designed for use with Potent Medical Electrohydraulic Lithotripter (TCS-B3-II) 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: K243032

Date Prepared: March 10, 2024

Device Name: EHL probe (SCDG -AS); EHL probe (SCDG -BS); EHL probe (SCDG -CS)

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: Area C, 4th Floor, Xinyin Industrial Village, Xintang Industrial Processing Zone, Xintang Town, 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: EHL probe (SCDG -AS); EHL probe (SCDG -BS); EHL probe (SCDG -CS)
- Model: SCDG -AS/ SCDG -BS/ SCDG -CS

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 SCDG -AS, SCDG -BS, and SCDG CS are sterile, single-use electrohydraulic lithotripsy (EHL) probes. These probes are designed to be used with the Electrohydraulic Lithotripter (TCS-B3-II) for the fragmentation of biliary calculi. The probes deliver low-energy electrical pulses through a dedicated connection to the generator, generating hydraulic shock waves in a saline medium to fragment stones in the biliary tract.

Key materials

- stainless steel, Polycarbonate (PC)
- Polytetrafluoroethylene (PTFE)
- Fluorinated Ethylene Propylene (FEP)
- Silver-plated Copper Wire
- Polyimide (PI)
- Perfluoroalkoxy (PFA)

The tip of each probe is the indirect-contacting patient component, designed for precise energy delivery.

V. Indications for use

The EHL probe is designed for use with Potent Medical Electrohydraulic Lithotripter (TCS-B3-II) for disintegration of concernments in the bile duct.

VI. Comparison of Technological Characteristics

- Energy Delivery Mechanism

Both the SCDG -AS, SCDG -BS, SCDG -CS probes and the predicate device use an electrohydraulic lithotripsy mechanism to generate hydraulic shock waves for bile duct stone fragmentation. These shock waves are produced by high-voltage pulses transmitted through the probe and directed at the target stones.

- Materials

Both devices use biocompatible materials, ensuring safety during patient contact.

SCDG - AS, SCDG -BS, SCDG -CS: Made from stainless steel, Polycarbonate (PC)

Polytetrafluoroethylene (PTFE)

Fluorinated Ethylene Propylene (FEP)

Silver-plated Copper Wire

Polyimide (PI)

Perfluoroalkoxy (PFA)

Predicative Device: Uses similar materials, with a focus on epoxy and metals, ensuring high durability and biocompatibility.

- Dimension

Although probe of potent medical is smaller than the probe of EL27-Compact in terms of total length, energy output line, therapeutic electrode length, and probe diameter, the core functionality remains unaffected due to identical structural composition, use of similar materials, the same energy delivery mechanism, and validated performance data. This confirms that dimensional change has not compromised its performance.

- Sterilization and Single-Use

Both sets of probes are sterile and intended for single-use, reducing contamination risks. They are sterilized using ethylene oxide (EO), ensuring effective sterility while maintaining material integrity.

- Biocompatibility

Both devices have undergone rigorous biocompatibility testing in compliance with ISO 10993-1. Testing includes cytotoxicity, sensitization Testing, irritation, acute systemic toxicity testing & material mediated pyrogenicity testing, ensuring that the probes are safe for patient contact.

VII. Performance Data

- Bench Testing:

In the process of validating the Electrohydraulic Lithotripsy (EHL) Probe, a comprehensive sequence of bench tests was conducted to verify the probe′s compliance with design specifications and its clinical efficacy. The tests prioritized safety, performance, and compatibility, structured as follows:

- Endoscope Compatibility Test: Probes were rigorously tested for compatibility with standard endoscopes, ensuring smooth insertion and operation without damaging the endoscope or the probe itself.
- Visual Inspection: Each probe underwent a meticulous visual inspection to identify any defects or deviations from the design specifications.
- Dimensional Verification: Critical measurements of the probes were taken to check that all dimensions fell within the tight tolerance limits specified in the design.
- Shockwave Efficacy: The ability of the probes to generate controlled and effective shockwaves was

evaluated.

- Electrode Durability Test: Monitoring the rate of electrode material consumption was pivotal in assessing the durability and longevity of the probes under normal usage conditions.
- Stone Fragmentation Test: Validated the system's ability to generate consistent high-voltage pulses and hydraulic shock waves capable of fragmenting biliary stones.
- Shock wave 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.
- Tissue perforation test: Comparative tissue perforation testing between TCS-B3-II and EL27-Compact using porcine bile duct.

These bench tests were not only fundamental in ensuring that the EHL Probe met all required regulatory standards but also in certifying its readiness for effective and safe clinical application. Each step of the testing process was carefully designed to challenge the probes under realistic conditions, thereby validating their performance and safety.

- Aging tests was conducted to validate the durability and service life of the probes under simulated use conditions. Testing demonstrated that the probes maintain consistent performance throughout their intended lifespan. The test is compliant with ASTM F1980.
- Electrical Safety and EMC Testing: The probes were tested for compliance with IEC 60601-1 (general safety) and IEC 60601-1-2 (EMC requirements) to ensure safety and electromagnetic compatibility when used with the TCS-B3-II Electrohydraulic Lithotripter.
- Biocompatibility Testing: biocompatibility evaluations, including cytotoxicity, sensitization Testing, irritation, acute systemic toxicity testing & material mediated pyrogenicity testing, were conducted according to ISO 10993-1/ ISO 10993-5/ISO 10993-10/ISO 10993-23/ ISO 10993-11. No adverse biocompatibility issues were identified.

The EHL probe was tested with its compatible Electrohydraulic Lithotriptor (TCS-B3-II) 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 SCDG -AS, SCDG

-BS, and SCDG -CS probes are substantially equivalent to the EL27-Compact(K230488). The minor differences in design and interface with energy generator source do not raise new questions of safety or effectiveness. Therefore, the probes are as safe and effective as the predicate device and are suitable for use in its intended clinical applications.