January 19, 2023

Lite-Med, Inc.
Walt Hsu
President & CEO
9th Floor, 49 Dongxing Road, Xinyi District
Taipei, 11070
Taiwan

Re: K213772
Trade/Device Name: LM-9300 Plus
Regulation Number: 21 CFR§ 876.5990
Regulation Name: Extracorporeal Shock Wave Lithotripter
Regulatory Class: II
Product Code: LNS
Dated: December 16, 2022
Received: December 21, 2022

Dear Walt Hsu:

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
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
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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)*
K213772

Device Name
LM-9300 Plus

Indications for Use *(Describe)*
The Lite-Med LM-9300 Plus Lithotripter is indicated for fragmentation of kidney stones such as renal calyx stones and renal pelvic stones and for upper ureteral stones by extracorporeal shock wave lithotripsy (ESWL).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 5. 510(k) Summary

510k Number: K213772

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

LITE-MED LM-9300 Plus Lithotripter

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the LM-9300 Plus is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices, which includes the following: Storz Medical AG-Modulith SLK (K120769).

I. SUBMITTER

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Date Prepared: January 06, 2023

II. DEVICE

Proprietary Trade Name: LM-9300 Plus
Common or Usual Name: Lithotripter, Extracorporeal Shock-Wave
Classification Name: Extracorporeal Shock Wave Lithotripter
Product Code: LNS
Regulatory Class: Class II with special controls
Regulation Number: 21 CFR 876.5990
Panel: Gastroenterology/Urology

III. PREDICATE DEVICE:

The Lite-Med LM-9300 Plus Lithotripter is substantially equivalent to the following currently marketed devices. For detailed information, please refer to section 12.

Storz Medical AG-Modulith SLK (K120769)

IV. Device Description

The Lite-Med LM-9300 Plus is an Electromagnetic Extracorporeal Shock Wave Lithotripter that effectively treats urinary calculi. It is routinely used for the fragmentation of kidney and ureteral stones and offers a good combination of clinical performance, flexibility and affordability. The standard LM-9300 Plus system consists of a shockwave generator, an operator interface (industrial PC with dual monitors), a water circulation subsystem and a patient handling subsystem. For the Extracorporeal Shock Wave Lithotripsy (ESWL) operation to be fully functional, two more optional subsystems are necessary. The first is a C-arm X-ray fluoroscopy device and the second is an ultrasound imaging unit. Normally one of the imaging devices is sufficient. For most advanced ESWL designs such as LM-9300 Plus both X-ray and ultrasound are used for patient positioning and monitoring purposes.

Shock waves are generated on the basis of a principle similar to that used in loudspeakers. An electrical impulse is sent through an inductance coil, generating a magnetic field which repulses a metallic membrane. The acoustic impulse created by this repulsion is focused by an acoustic lens to form a shock wave. A water circulation subsystem is used to provide transmission of shockwaves and cooling of the generator.

V. INDICATION FOR USE

The Lite-Med LM-9300 Plus Lithotripter is indicated for fragmentation of kidney stones such as renal calyx stones and renal pelvic stones and for upper ureteral stones by extracorporeal shock wave lithotripsy (ESWL).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Lite-Med LM-9300 Plus has the same technological characteristics as the predicate. The shock wave characteristics are measured by taking the guideline “Guidance for the Content of Premarket Notifications 510(k)s for Extracorporeal Shock Wave Lithotripters Indicated for the

Fragmentation of Kidney and Ureteral Calculi" described in the consensus standard IEC 61846 "Ultrasonics – Pressure pulse lithotripters – Characteristics of fields" (1998) into consideration. Fiber Optic Probe Hydrophones are used in the measurements. The details of the measurements/calculations are given in relevant part of 510(k) application. The results are found similar to the predicate device characteristics.

Technical Elements:

1. Shock wave generation type: Electromagnetic
2. Shock wave used for fragment stone
3. Use of a water cushion to deliver energy
4. Treatment table used for moving patient position
5. X-ray and Ultrasound used for localization

The following technological differences exist between the subject and predicate devices:

1. Use of different x-ray system
2. Use of different ultrasound scanner

VII. PERFORMANCE DATA

Non-Clinical Performance Data

The LM-9300 Plus is in accordance with the following safety and performance requirements, and provided in support of substantial equivalence:

- Electrical Safety and EMC
  - IEC60601-1
  - IEC60601-1-2
  - IEC 60601-2-36
  - IEC61846
  - IEC62366
  - ISO14971

- Software Verification and Validation Testing
  - IEC62304
  - IEC/TR80002-1

Clinical Performance Data

Clinical performance is not required to demonstrate substantial equivalence to the predicate devices.

VIII. CONCLUSIONS

From a clinical perspective and comparing design specifications, the LM-9300 Plus is substantially equivalent to the predicate devices. The LM-9300 Plus meets the FDA requirements stated in “Guidance for the Content of Premarket Notifications 510(k)s for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi” issued on Aug. 9, 2000. Lite-Med Inc. believes the minor differences of the LM-9300 Plus and its predicate devices should not raise any concerns regarding the overall safety or effectiveness.