June 16, 2025

Shenzhen Wikkon Precision Technologies Co., Ltd.
% Yijie You
General Manager
Qimmiq Medical Consulting Service Co., Ltd.
RM.406, Building C, Run Science Park, No.18 Shenzhou Road,
Huangpu
Guangzhou, Guangdong 510663
CHINA

Re: K242922
Trade/Device Name: Extracorporeal Shock Wave Lithotripter (U200)
Regulation Number: 21 CFR 876.5990
Regulation Name: Extracorporeal Shock Wave Lithotripter
Regulatory Class: Class II
Product Code: LNS
Dated: May 14, 2025
Received: May 15, 2025

Dear Yijie You:

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,

Mark J. Antonino -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, 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)*

K242922

Device Name

Extracorporeal Shock Wave Lithotripter (U200)

Indications for Use *(Describe)*

The Extracorporeal Shock Wave Lithotripter, model: U200, is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

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) #: K242922

510(k) Summary

Prepared on: 2025-06-17

Contact Details

21 CFR 807.92(a)(1)

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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Extracorporeal Shock Wave Lithotripter (U200)
Common Name	Extracorporeal shock wave lithotripter
Classification Name	Lithotriptor, Extracorporeal Shock-Wave, Urological
Regulation Number	876.5990
Product Code(s)	LNS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K103217	Extracorporeal Shock Wave Lithotripter, LM-9200 ELMA	LNS

Device Description Summary

21 CFR 807.92(a)(4)

The Extracorporeal Shock Wave Lithotripter, U200, is intended to treat urinary tract stones using ESWL. The Extracorporeal Shock Wave Lithotripter generates high-energy shock waves using a shock wave generator that is focused to produce a highly concentrated stress area at the focal point. These pressure pulses are focused on a specific point in the body where the Urinary calculi are located using

assisted movement and manual localization through B-ultrasound. The pressure generated by the shock wave causes the human urinary tract stones to produce physical effects to achieve the therapeutic purpose of crushing stones.
The Extracorporeal Shock Wave Lithotripter, U200, is composed of main unit, control console, patient table, electrical cabinet, power supply unit, and computer.
Control platform is integrated control of electric cabinet, main engine and treatment bed.
Electrical cabinet is used to provide power control of the whole machine, and shock wave source function control.
Main Unit contains the L-shape arm and the support matrix of the impact wave source, and realize the movement of L-shape arm up and down, rotation and oscillation of the impact wave source inside and outside.
Power box is power supply of the whole machine, power supply input voltage 120 V, 60 Hz, 3000 VA.
Treatment bed is used for patient support and treatment position, and provides three-dimensional movement to allow easy positioning of the stone in the shock wave focus for lithotripsy and urological procedures.
PC(OptiPlex 7000 Tower) is used for installation of Extracorporeal Shock Wave Lithotripter Computer Control System, and to realize the Movement Control Support Function and the calibration of shock wave target, and image handling.
Principle of operation:
The extracorporeal shock wave lithotripter generates pressure pulses using an electromagnetic shock wave generator, with water serving as the transmission medium. These high energy shock waves with peak acoustic pressure up to 35MPa are focused on a specific point using a lens. In addition, the lithotripter often incorporates an ultrasound-based assisted movement system which locates and aligns the shock wave focus with the urinary tract stone. The shock waves create a stress effect on the stone. After several hundred to around two thousand discharges, the stones are fragmented into smaller pieces which can be excreted from the body.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Extracorporeal Shock Wave Lithotripter, model: U200, is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

Indications for Use Comparison

21 CFR 807.92(a)(5)

The proposed device, model: U200, has the same indication for use as the primary predicate device Extracorporeal Shock Wave Lithotripter (model: LM-9200 ELMA).

Technological Comparison

21 CFR 807.92(a)(6)

The proposed device, model: U200, has the similar characteristics as the primary predicate device Extracorporeal Shock Wave Lithotripter (model: LM-9200 ELMA), such as control console, shock wave generator, Water System,Localization/Imaging System, Patient Table, and acoustic Output Characteristics . Moreover, the bench testing and clinical testing contained in this submission supplied demonstrate that the differences existed between U200 and the primary predicate device Extracorporeal Shock Wave Lithotripter (model: LM-9200 ELMA), do not raise any new questions of safety or effectiveness. Thus, extracorporeal Shock Wave Lithotripter, model: U200, is Substantially Equivalent (SE) to the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Shenzhen Wikkon performed performance testing to demonstrate and support safety and effectiveness when compared to the predicate and the applicable standards.
The following non-clinical testing was provided in this 510(k) submission:
1) Biocompatibility Testing
According to ISO 10993-1:2018, we performed the biocompatibility evaluation and test of skin surface direct-contacting components with duration of less than 24 hours.
(1) In vitro Cytotoxicity test according to ISO 10993-5:2009
(2) Skin Sensitization test according to ISO 10993-10:2021 tested
(3) Irritation test according to ISO 10993-23:2021 tested

2)Electrical Safety and Electromagnetic Compatibility Testing
The Device was tested and complied with the applicable requirements of the following standards: ANSI AAMI ES60601-1, IEC 60601-1-2, IEC 60601-2-36 and IEC 61846 demonstrated that the basic safety and performance of the device met the requirements.

3)Software Verification and Validation
Software verification and validation was performed, and it was demonstrated that the software performs as intended according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
Cybersecurity verification and validation was performed, and it was demonstrated that the cybersecurity performs as intended according to the FDA Guidance for Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.

4)Shock Wave Characterization Measurements testing
The acoustic output characteristics performance with minimum, typical, and maximum shock wave generator output settings of Extracorporeal Shock Wave Lithotripter(model: U200) was tested and complied with the applicable requirements of the standards of IEC 61846 demonstrated that the performance of the device met the requirements.

5)Assessment of Localization Accuracy testing
The maximum deviation of the "target location" from the "shock wave focus" for the localization/stone targeting system was verified to demonstrate the localization/stone targeting system is capable of locating the shock wave focus with sufficient accuracy to target stones as performance claimed.

The clinical investigations adopted a multicenter, open-label clinical design to confirm the functionality and labeling adequacy of the U200 Extracorporeal Shock Wave Lithotripter
A total of 29 subjects were screened in the two centers, 4 subjects failed to be screened, 25 subjects were enrolled, 22 subjects completed the study, and 3 subjects dropped out, with a dropout rate of 12%. The U200 Extracorporeal Shock Wave Lithotripter was used to treat urinary tract stones by ESWL. The stones sizes treated were between 0.5 cm and 1.5 cm. Using ultrasound assisted movement function, the device focuses shock waves on a specific point within the body where the stone is located and break the stone into pieces by the physical forces created by the shock waves. Patients were followed for a period of follow-up 2(Day 14 ± 2 days after Treatment 1) and Follow-up 4 (Day 14 + 2 days after Treatment 2).
When using the research device for lithotripsy treatment, the auxiliary positioning target error of the treatment is within 3mm, the number of auxiliary positioning operations is within 3 times, and the total time of auxiliary positioning operations is within 15min.The positioning operation of the research device is relatively fast, accurate, and convenient, and the system ergonomics performance is good.
Primary effectiveness endpoint:
After the subjects completed the treatment, the effective rate of FAS was 79.2%, the effective rate in the PPS was 86.4%.
In the Full Analysis Set, there were 14 subjects with stones between 5 and 10 mm in long axis, the treatment effective rate of 92.9%, and there were 10 subjects with stones between 10~15mm in long axis, the treatment effectiveness rate of 60.0%.
In the Per-Protocol Set, there were 13 patients with stones between 5 and 10 mm in long axis, the treatment effective rate was 100%. There were 9 subjects with stones between 10~15mm in long axis, the treatment effective rate was 66.7%.
In the Full Analysis Set, there were 10 cases of kidney stones, the treatment efficiency was 80.0%, the treatment efficiency of the renal calyx stones was 75.0%,and the treatment efficiency of the renal pelvis stones was 100%; there were 14 cases of ureteral stones, the treatment efficiency was 78.6% among which the treatment efficacy of upper ureteral stones was 70.0%,that of middle ureteral stones was 100%, and that of lower ureteral stones was 100%.
In the Per-Protocol Set, there were 10 subjects with kidney stones, the treatment efficiency of 80.0% among which the treatment efficiency of renal calyx stones was 75.0%,and that of renal pelvis stones was 100%; and there were 12 subjects with ureteral stones, the treatment efficiency of 91.7% among which the treatment efficiency of upper ureteral stones was 87.5%,that of middle ureteral stones was 100%,and that of lower ureteral stones was 100%.
In the Full Analysis Set, there were 2 subjects with a stone density less than 500HU, the treatment effectiveness rate of 50%. There were 11 subjects with stone density between 500 and 1000 HU, the treatment effective rate was 81.8%. There were 11 subjects with a stone density greater than 1000 HU, the treatment effective rate of 81.8%.
In the Per-Protocol Set, there were 2 subjects with a stone density less than 500HU, the treatment effectiveness rate of 50%. There were 9 subjects with a stone density between 500 and 1000 HU, the treatment effectiveness rate of 100%. There were 11 subjects with a stone density greater than 1000 HU, the treatment effective rate of 81.8%.
The experiences of physicians have shown that patients treated by the Extracorporeal Shock Wave Lithotripter (model: U200) are safe and having high evaluations for the device function. And the user's manual is adequate for the operation of Extracorporeal Shock Wave Lithotripter, model: U200. The incidence of device malfunction does not happen in these clinical investigations.
Based on the clinical performance as documented in the clinical study, the Extracorporeal Shock Wave Lithotripter (model: U200) was found to have a safety and effectiveness profile that is similar to the predicate device.

The proposed device, model: U200, has the same intended use and similar characteristics as the primary predicate device Extracorporeal Shock Wave Lithotripter (model: LM-9200 ELMA). Moreover, bench testing and clinical testing contained in this submission supplied demonstrate that the differences existed between U200 and the primary predicate device Extracorporeal Shock Wave Lithotripter (model: LM-9200 ELMA), do not raise any new questions of safety or effectiveness. Thus, extracorporeal Shock Wave Lithotripter, model: U200, is Substantially Equivalent (SE) to the predicate devices.