



May 10, 2024

Shenzhen HugeMed Medical Technical Development Co., Ltd.
% Jie Yang
Consultant
Shenzhen Chonconn Medical Device Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong
CHINA

Re: K240374
Trade/Device Name: Ureterorenoscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Received: April 19, 2024

Dear Jie Yang:

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.

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

OHT3: Office of Gastrorenal, ObGyn,

General Hospital, and Urology Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K240374

Device Name

Ureterorenoscope System

Indications for Use (Describe)

The Ureterorenoscope System has been designed to be used with endo-therapy accessories such as a biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within urinary tract and interior of the kidney.

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) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

The assigned 510(k) number: K240374

Prepared Date: 2024/04/19

1. Submission sponsor

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3. Subject Device Information

Trade/Device Name	Ureterorenoscope System
Model	single-use Ureterorenoscope: HU30S image processor: HUV-01
Common Name	Endoscope and accessories
Regulatory Class	Class II
Classification	21CFR 876.1500 / Ureterscope And Accessories, Flexible/Rigid / FGB
Submission type	Traditional 510(K)

4. Predicate Device

510(k) number: K230475

Product name: Medical Video Endoscope System

Product code: FGB

5. Device Description

The Ureterorenoscope System consists of a single-use Ureterorenoscope(HU30S) to provide illumination and intuitive images in endoscopy and endoscopic surgery within urinary tract and interior of the kidney and serves as a guide to diagnosis and management

with accessories and an image processor, previous clearly by K231118, for clinical image processing.

The single-use Ureterorenoscope is comprised of a control body with articulation controls and accessory access ports, and a flexible insertion tube with an on-tip camera module and LED lighting source. The image processor processes the images from the Ureterorenoscope and outputs video signals to a display.

6. Intended use & Indication for use

The Ureterorenoscope System has been designed to be used with endo-therapy accessories such as a biopsy forceps and other ancillary equipment for endoscopy and endoscopic surgery within urinary tract and interior of the kidney.

7. Comparison to the Predicate Device

The device has the same sterilization method, energy source, principle of operation and similar design with same parameters such as FOV, DOV, deflection angle etc. They have similar technological characteristics as below. These differences will not raise new question on safety and effectiveness of the proposed device.

1. Depth of view of the proposed Ureterorenoscope is within the range of the predicate device.
2. The Max. outer diameter of insertion section of the proposed Ureterorenoscope is slight thinner than the predicate device.
3. The proposed Ureterorenoscope evaluated the biocompatibility based on more strict risk classification with two more testing including Acute Systemic Toxicity and Material-mediated Pyrogens.
4. The proposed image processor has slightly different dimensions and weight compared with the predicate device due to different outlook design.
5. The proposed image processor has more types of signal output than the predicate device to give physicians more usage options.

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Biocompatibility of the single-use Ureterorenoscope was evaluated in accordance with the FDA guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1:

Evaluation and Testing Within a Risk Management Process,” as recognized by FDA.

Sterilization and shelf life testing

The Single-use Ureterorenoscope is provided sterile and its shelf-life is 3 years.

Sterilization Process has been validated accordance with ISO 11135:2014.

EO/ECH residual test was performed according to ISO 10993 - 7:2008.

The shelf life is determined based on optical testing and product performance testing after accelerated aging test according to ASTM F1980 - 16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

Package validation was conducted according to ISO 11607 - 1:2019 and ISO 11607 - 2:2019, and ASTM F1886/F1886M-16, ASTM F88/F88M - 15, ASTM F 1929 - 15.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Ureterorenoscope System. The system complies with the IEC 60601-1 and IEC60601-2-18 for safety and the IEC 60601-1-2 for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Content of Premarket Submissions for Device Software Functions”.

Bench performance testing

The following bench tests were performed:

1. Optical performance testing according to ISO 8600 series.
2. Color performance (color reproduction), geometric distortion, optical performance (resolution, depth of field and image intensity uniformity), SNR and dynamic range, image frame frequency and system delay test compared with the predicate device.
3. Mechanical testing including water resistance, deflection, leakage and flow rate.

9. Clinical study

Not applicable.

10. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the proposed Ureterorenoscope system is substantially equivalent to the predicate device.