October 21, 2025

Shenzhen Sanping Image Technology Co., Ltd.
% Chen Salon
System engineer
IMD Medical & Drug technology service institutions
Room 308, Building 11, No. 23 Jinqu Road, Wanjiang District
Dongguan, Guangdong 523000
CHINA

Re: K250917
Trade/Device Name: Flexible Ureterorenoscope system (Electronic Endoscope Image Processor, model: SP-TXCLQ12.1, Flexible Ureterorenoscope, model: SP-SNGSYJ 2.0, SP-SNGSYJ 2.2, SP-SNGSYJ 2.5, SP-SNGSYJ 2.8)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: March 27, 2025
Received: September 29, 2025

Dear Chen Salon:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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
OHT3: Office of Gastrorenal, ObGyn,
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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)*
K250917

Device Name
Flexible Ureterorenoscope system (Electronic Endoscope Image Processor, model: SP-TXCLQ12.1, Flexible Ureterorenoscope, model: SP-SNGSYJ 2.0, SP-SNGSYJ 2.2, SP-SNGSYJ 2.5, SP-SNGSYJ 2.8)

Indications for Use *(Describe)*
The device is intended to be used with endoscopic accessories such as a biopsy forceps and Electronic Endoscope Image Processor for endoscopy and endoscopic surgery within urinary tract and interior of the ureter and 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

1. Sponsor Identification

- Company Name: Shenzhen Sanping Image Technology Co., Ltd.
- Address: Room 203, No.634, Shajing Road, Buchong Community, Shajing Street, Bao'an District, Shenzhen, China
- Phone: +86-755- 23223975
- Fax: +86-755- 23223975
- Contact Person (Title): Vincent Pan (General Manager)
- E-mail：vincent.pan@it-looker.com
- Date of Preparation: October 21, 2025

2. Device Name and Classification

- Trade Name: Flexible Ureterorenoscope system (Electronic Endoscope Image Processor, model: SP-TXCLQ12.1, Flexible Ureterorenoscope, model: SP-SNGSYJ 2.0, SP-SNGSYJ 2.2, SP-SNGSYJ 2.5, SP-SNGSYJ 2.8)
- Regulation Name: Endoscope and accessories
- Classification Product Code: FGB
- Regulation Number: 21 CFR 876.1500
- Class: 2
- Review Panel: Gastroenterology/Urology
- Common Name: Ureteroscope and Accessories, Flexible/rigid

3. Predicate Device Information

- 510(k) Number: K221158
- Regulation Name: Endoscope and accessories

- Sponsor: Guangzhou Red Pine Medical Instrument Co., Ltd.
- Classification Product Code: FGB
- Regulation Number:21 CFR 876.1500
- Class: 2
- Review Panel: Gastroenterology/Urology
- Trade/Proprietary Name: Single-Use Video Flexible Ureterorenoscope System
- Common Name: Ureteroscope and Accessories, Flexible/rigid

4. Application Correspondent

- Company Name: IMD Medical & Drug technology service institutions
- Phone: +86-18613190779
- Fax: +86-755-62809168
- Contact Person (Title): Salon Chen (System engineer)
- E-mail：33999439@qq.com
- Address: Room 308, Building 11, No. 23 Jinqu Road, Wanjiang District, Dongguan City, Guangdong Province, China

5. Device Description

The Flexible Ureterorenoscope System consists of a sterile Flexible Ureterorenoscope and an Electronic Endoscope Image Processor with its accessories power adapter. The Flexible Ureterorenoscope is provided sterile (sterilized by EO) and is single use.

The Flexible Ureterorenoscope consists of a head section, bending section, insertion section, operating section, electrical connection section, and built-in LED light source. The Electronic Endoscope Image Processor is powered by the main line.

The Flexible Ureterorenoscope is an endoscope instrument and is intended to be used with the Electronic Endoscope Image Processor during endoscopic procedures. The handle section features

several key components, including a control lever, a handle for manipulation, a button for capturing photos or video, and a Luer port for the insertion of accessories or irrigation to the working channel. The insertion section houses a working channel and wiring to transmit the image signals to the image processor. The distal bending section of the insertion section contains a camera lens for real-time image capture, an LED light source for illumination, and a distal outlet for the working channel. The Electronic Endoscope Image Processor is a video processor which is intended and designed for use during endoscopic procedures. It receives and processes image signals from the endoscope and outputs signals to an external medical monitor for display.

The Electronic Endoscope Image Processor has integrated software to control the operation of the device and is a reusable device that does not require sterilization before use, as there is no direct/in-direct patient contact material. The image processor is intended to be cleaned and disinfected before use, the cleaning and disinfection method is validated and recommend in the User Manual.

The equipment is for use in a hospital or qualified medical institution. It is only to be used by skilled physicians trained in clinical endoscopic techniques and procedures.

6. Indications for Use

The device is intended to be used with endoscopic accessories such as a biopsy forceps and Electronic Endoscope Image Processor for endoscopy and endoscopic surgery within urinary tract and interior of the ureter and kidney.

7. Comparison to the predicate device

Table 1 General Comparison

Elements of Comparison	Proposed Device	Predicate Device K221158	Judgment
Company Name	Shenzhen Sanping Image Technology Co., Ltd.	Guangzhou Red Pine Medical Instrument Co., Ltd.	/

Device Name	Flexible Ureterorenoscope system	Single-Use Video Flexible Ureterorenoscope System	/
Classification Product Code	FGB	FGB	SE
Regulation	21 CFR 876.1500	21 CFR 876.1500	SE
Classification Name	Endoscope and accessories	Endoscope and accessories	SE
Review Panel	Gastroenterology/Urology	Gastroenterology/Urology	SE
Class	2	2	SE
Prescription or OTC	Prescription Use	Prescription Use	SE
Anatomical Sites	Urinary tract and interior of the kidney	Urinary tract and interior of the kidney	SE
Target Population	Adults	Adults	SE
Where used	Hospital	Hospital	SE

Intended Use	The device is intended to be used with endoscopic accessories such as a biopsy forceps and Electronic Endoscope Image Processor for endoscopy and endoscopic surgery within urinary tract and interior of the ureter and kidney.	The device is intended to be used with endoscopic accessories such as a biopsy forceps and Endoscopic Video Image Processor for endoscopy and endoscopic surgery within urinary tract and interior of the ureter and kidney.	SE

Table 2 Safety factor & Performance Comparison

Safety factor & Performance	Proposed Device	Predicate Device	Judgment
Electrical Safety	Compliance with IEC 60601-1	Compliance with IEC 60601-1	SE
EMC	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	SE
Usability Engineering	Compliance with IEC 62366-1	Compliance with IEC 62366-1	SE
Biocompatibility	Compliance with ISO 10993-1	Compliance with ISO 10993-1	SE
Type of Scope	Flexible	Flexible	SE
Type of Imager	CMOS	CMOS	SE
Light Source	LED	LED	SE
Up/Down Deflection (°)	Up: 270 Down: 270	Up: 275 Down: 275	Note 1
Direction of View (°)	0	0	SE
File of View (°)	120	120	SE

Safety factor & Performance	Proposed Device	Predicate Device	Judgment
Maximum insertion portion width (mm)	SP-SNGSYJ 2.8: 3.2 SP-SNGSYJ 2.5: 2.9 SP-SNGSYJ 2.2：2.7 SP-SNGSYJ 2.0：2.3	RP-U-C12: 3.2 RP-U-C0304: 3.15 RP-U-C0305: 3.18	Note 2
Working Length(mm)	650	670	Note 3
Minimum instrument channel width (mm)	0.8	1.2	Note 4
Depth of Field (mm)	3 - 50	3 - 50	SE
System composition	Flexible Ureterorenoscope and Electronic Endoscope Image Processor	Single-use video flexible Ureterorenoscope and Endoscopic Video Image Processor	SE
General material type of main patient-contact	Compliance with ISO10993 - 1	Compliance with ISO10993 - 1	SE
Duration and type of contact	“Surface –Surface Device: Breached or Compromised” with a contact duration of “Limited (< 24 hours)”	“Surface –Surface Device: Breached or Compromised” with a contact duration of “Limited (< 24 hours)”	SE
Number of Users	Single-Use	Single-Use	SE
Sterilization	EO Sterilized, SAL 10^{-6}	EO Sterilized, SAL 10^{-6}	SE

Review of Differences：

Note1:

There are differences in the Up/Down Deflections compared to the predicate. However, they are in close proximity to each other and the deflection range of the proposed device falls within the

window defined by the predicate. Therefore, such a difference does not raise different questions of its safety and effectiveness.

Note2:

There are differences in the Maximum insertion portion width as compared to the predicate. The proposed device has a smaller inserting outer diameter (OD) than the predicate, which is advantageous for the clinical use. Therefore, this variance does not raise different questions of its safety and effectiveness.

Note3:

The subject and predicate devices have similar principles of operation, scope, imager, light source, sterilization method, and the number of users/environments.

There is slight difference in the working length as compared to the predicate. According to the structure of the human ureter, its length is generally 250-300mm. The working length of the designed endoscope should be greater than this parameter to be effectively used clinically. The working length of the insertion part of the endoscope designed by our company is 650mm. The designed working length can reach the intended anatomical location for treatment, meeting the clinical use needs of most people. The working length of the insertion part of the comparative product is 670mm. The working length of the declared product differs from that of the comparative product by 20mm, and the difference accounts for only 3% of the total working length. During operation, the slight length difference can be compensated for by adjusting the insertion angle of the endoscope or the patient's body position. Therefore, this variance does not raise different questions of its safety and effectiveness.

Note4:

Although there is a difference in the channel specifications between our company's device with a 0.8mm channel and the comparative device, both can achieve the same clinical objectives：

1）Instrument Compatibility: The endoscope with a 0.8mm channel can be adapted to ultra-thin instruments. For example, the endoscope with a 0.8mm channel can be used together with micro-instruments such as micro-guidewires with a diameter of less than 0.6mm and laser optical

fibers. The endoscope with a 1.2mm channel can support the passage of slightly thicker instruments, and their clinical functional scopes overlap.

2）Consistent Clinical Applications: The endoscopes with both channel specifications are suitable for the same indications, such as the examination of narrow lumens, the observation and marking of the diseased areas, etc. Moreover, the endoscope with a 0.8mm channel has a thinner endoscope body, which can enter narrower diseased areas for examination.

3）Safety: The performance and safety of the declared endoscope have been verified and confirmed, and the results all meet the requirements.

The design of the endoscope with a 0.8mm channel by our company is the result of continuous technological optimization. It has the same intended use and clinical functions as the comparative devices. This difference does not affect the substantial equivalence, and the thinner endoscope body can improve the pass ability in narrow lumens, which may be beneficial for clinical use.

8. Nonclinical testing summary

Electrical Safety and Electromagnetic Compatibility Summary

The electrical safety and EMC data included in the submission are compliance with the following FDA recognized standards:

--IEC 60601-1-2:2014 /AMD1:2021 Medical Electrical Equipment -- Part 1-2: General Requirements for Basic Safety and Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements and Tests.

--IEC6060-1:2005+A1:2012+A2:2020 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.

---IEC 60601-2-18:2009, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.

Photobiological safety

The subject device is tested according to the following FDA recognized standards:

--IEC 62471:2006 Medical electrical equipment, Photobiological safety of lamps and lamp systems

Bench Testing Summary

The subject device was designed to comply with applicable parts of ISO 8600- 1:2015. Optical measurements were performed according to applicable part of ISO 8600-1:2015, ISO 12233:2017 and ISO 15739:2017 standard.

The system performance tests were performed including up/down deflection (°), repeated flexing, water supply system, sealing performance, normal working condition, file of View (°), direction of view (DOV), geometric distortion, Signal-To-Noise Ratio, Image Intensity Uniformity (IIU), and color performance.

Software Verification and Validating Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern.

Biocompatibility Summary

Biocompatibility evaluation for Flexible Ureterorenoscope system was conducted in accordance with the FDA Guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The following tests were conducted based contact category of "Surface – Mucosal Membrane" with a contact duration of "Limited (< 24 hours):

--ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

--ISO 10993-10:2021 Biological evaluation of medical devices - Parts 10: Tests for skin sensitization

--ISO 10993-11:2017 Biological evaluation of medical devices, Part 11: Tests for systemic toxicity

--ISO 10993-23:2021 Biological evaluation of medical devices-Parts 10: Tests for irritation

Sterilization and Shelf-Life Testing

Sterile barrier systems were evaluated in accordance with ISO 11607:2019. 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 of the Flexible Ureterorenoscope system is determined based on stability study which includes ageing test according to ASTM F1980-16 and ASTM F 1980- 07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

Packaging Validation

Package validation was conducted according to ISO 11607-1:2019 、ISO 11607-2:2019、 ASTM F1929-98、ASTM F1140-07 and ASTM F88.

The collective results of Non-clinical testing demonstrate that the materials chosen, the manufacturing processes and design of the Flexible Ureterorenoscope system meets the established specifications necessary for consistent performance during its intended use. In addition, the Bench Test results demonstrate that compared with the predicate, the Flexible Ureterorenoscope system has the same or similar image quality, optical performance and mechanical performance.

9. Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

10. Conclusion

The subject devices have all features of the predicate devices. The few differences do not affect the safety and effectiveness of the subject devices. Thus, the subject device is substantially equivalent to the predicate device.