October 26, 2026

Hangzhou Hawk Optical Electronic Instruments Co., Ltd.
Lieqing Zhang
QA Vice Manager
#9 Xinda Rd., Suoqian, Xiaoshan
Hangzhou, Zhejiang 311201
CHINA

Re: K260350
Trade/Device Name: Cysto-Urethroscopes and accessories (PG-VC)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FJL, KQT
Dated: September 29, 2026
Received: September 29, 2026

Dear Lieqing Zhang:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 R. Kreitz -S

for 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260350

Please provide the device trade name(s).

Cysto-Urethroscopes and accessories

Please provide your Indications for Use below.

For the transurethral treatment of Benign Prostatic Hyperplasia (BPH) in adult males.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

Manufacturer: Hangzhou Hawk Optical Electronic Instruments Co., Ltd
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Date of Summary was prepared: 2026-10-23

Identification of the Device:

Proprietary/Trade Name:	Cysto-Urethroscopes and accessories(K260350)
Common Name	Endoscope and Accessories
Classification Name:	Resectoscope
Regulation Number:	21 CFR 876.1500
Regulatory Class:	Class II
Product code:	FJL,FEC,FDC,KQT
Review Panel:	Gastroenterology/Urology

Primary Predicate Device:

Proprietary/Trade Name:	Morce Scope Set (K041610)
Common Name	Endoscope and Accessories
Classification Name:	Resectoscope
Regulation Number:	21 CFR 876.1500
Regulatory Class:	Class II
Product code:	FJL
Review Panel:	Gastroenterology/Urology

Reference Device:

Proprietary/Trade Name:	Resectoscopes,Instruments and Accessories E-line(K980302)
Common Name	Hysteroscope and accessories
Classification Name:	Hysteroscope (and accessories)
Regulation Number:	21 CFR 876.1500

Regulatory Class: Class II

Product code: HIH

Review Panel: Gastroenterology/Urology

1. Device Description

1.1. Construction and consist

Cysto-Urethroscopes and accessories consist of endoscope, Outer Sheath,Inner Sheath, Obturator, Working Element and Adaptor for Ellik as below shows.

REF	Name	Description	Laser Enucleation		Tissue Morcellation	
			26Fr.	24Fr.	26Fr.	24Fr.
Y6236 5H	Telescope 0°	Instrument Channel Φ5 mm,13.4Fr.x191 mm,autoclavable			√	
Y6236 6H	Telescope 0°	Instrument Channel Φ5 mm,10.2Fr.x191 mm,autoclavable				√
TH3315 1	Telescope 25°	Φ4x302 mm,Autoclavable	√	√		
N5810B-1	Outer Sheath	26 Fr.x180 mm	√		√	
N5810 H	Outer Sheath	24 Fr.x180 mm		√		√
N5815-2	Inner Sheath	24 Fr.x199 mm	√			
N5815 H	Inner Sheath	22 Fr.x199 mm		√		
N5820A	Obturator	Use with 26 Fr. Outer Sheath	√		√	
N5820F	Obturator	Use with 24Fr. Outer Sheath		√		√
N5821A	Obturator	Use with 24 Fr. Inner Sheath	√			
N5821 F	Obturator	Use with 22 Fr. Inner Sheath		√		
N5800B-7	Working Element	Passive,use with 550μm laser fiber	√			
N5800 F-1	Working Element	Passive,use with 550μm laser fiber		√		
P1012F	Adapter for ELLIK		√	√		

1.2. Function and Principles of operation

Device covered in this documents are used in laser enucleation of the prostate(Laser TURP) and with mechanical tissue morcellation, this is one of the high effective surgical modalities for the treatment of BPH.This operation is divided into two steps.

First, laser enucleation of the prostate.

Outer sheath,Inner Sheath and obturator connected and insert urethra. Then, the obturator is removed and the telescope and working element is inserted into the Inner sheath,laser fiber insert through the tube of working element.
During the process of enucleating the prostate using a laser fiber, the surgeon manipulates the working element to control the laser fiber, enucleating the entire prostate lobe from the surgical capsule and displacing it into the bladder like below picture shows.

After the laser enucleation procedure is completed, the inner sheath and working element will be pulled out, and then a endoscope, such as the Y6236 5H or Y 6236 6H will be connected to the outer sheath， and then an electrically driven blade will be inserted into the Outer sheath through instrument channel of the endoscope to crush the large piece of prostate. During the crushing process, the tissue will be sucked out through the blade. When in clinical use,the endoscope will be connected with video processor and light source.

1.3. Material

Subject devices made with following material.

Material	Used in the devices
304 stainless steel n conformance with ASTM F899-20	Main part of all the devices
Glass	Lens of endoscope
Zirconia	Distal tip of inner sheath
Silicone Rubber	O ring of outer sheath
PTFE	White slide block of working element
PPSU	Plastic cup of outer sheath and eyecup of endoscope

1.4. Duration of products with patient

Cysto-Urethroscopes and accessories is categorized as a surface device contacting a breached or compromised surface for a limited duration (< 24 hours).

2. Indications for Use

	Indication for Use
Subject devices	For the transurethral treatment of Benign Prostatic Hyperplasia (BPH) in adult males.
Predicate device	Benign prostatic hyperplasia,kidney and bladder stones via percutaneous,tumors via percutaneous (kidney) or transurethral (bladder)

Subject device has less indication due to subject device should align with compatible YSB-IIIA morcellator.

3. Technological Comparison

The subject device has the same construction , principle of operation as the legally marketed Morcescope Set (K041610) and Resectoscopes,Instruments and Accessories E-line(K980302), A side by side comparison of the subject device and the predicate device is provided in Table 1.

Table 1 Comparison of the Subject and Predicate Device

Item	Subject Device	Predicate Device Morce Scope Set (K041610)	Conclusion
Intended use	The Cysto-Urethroscope and accessories, use with a laser fiber for tissue cutting or with a morcellator probe for tissue morcellation.	The Morce Scope Set,in conjunction with a morcellation probe,and with its sheaths and obturators ,is used in cutting(morcellation) and continuous removal of large detached tissue masses. In combination with the corresponding auxiliary instruments, it can be used as a nephroscope in the disintegration and removal/aspiration of kidney and bladder stones and the removal of tumors via percutaneous (kidney) or transurethral (bladder) passages, in conjunction with intracorporeal lithotriptors e.g. operated pneumatically, by ultrasound, electro-hydraulically or by laser, under endoscopic control. The POWER CONTROL 2303 in conjunction with POWER STICK M4 serves to drive WOLF morcellators for the continuous removal of ablated tissue in endoscopic operations. The SUCTION PUMP is used for aspirating irrigation fluid in conjunction with a resectoscope or a morcellator following laser TURP.	Subject device has Narrow intended use due to subject device should align with compatible YSB-IIIA morcellator.
Outer Dimensions of continuous irrigation outer sheath	24Fr,26Fr	24Fr, 24.5Fr, 26Fr	Same
Channel for Maximum blade	Φ4.8 mm	Φ4.8 mm	Same
Configuration	Telescope,outer sheath,inner sheath,obturator,working element	Telescope,outer sheath,obturator	Same The reference device contain working element.
Main material	304 stainless steel	Stainless steel	Same
Device use settings	Hospital	Hospital	Substantial

4. Non-Clinical performance Testing

4.1. Comparison testing

In order to support a determination of substantial equivalence,Hawk has completed following comparison testing.

- Dimension
- FOV,DOV according to ISO 8600-3(Method B)
- MTF resolution and depth of field according to ISO 12233: 2023
- Image distortion according to https://doi.org/10.1117/1.JBO.21.5.056003
- Image intensity uniformity according to ISO 17957:2015
- Spectral Transmission.The spectral transmission of the endoscope was evaluated by comparing the output spectra measured with and without the endoscope in the optical path. A calibrated spectral analyzer was used to first record the reference spectrum of the cold light source coupled directly to the light guide cable, and then measure the spectrum emitted from the endoscope with the light guide cable attached, under identical conditions. The spectral transmittance T(λ) was calculated as the wavelength-by-wavelength ratio of the endoscope output spectrum to the reference spectrum, and the luminous transmittance was derived as the ratio of the photopic luminous fluxes, each obtained by weighting the measured spectral data with the CIE 1931 photopic response V(λ) and integrating over the visible spectrum.
- A mechanical study on the insertion and withdrawal force of the outer sheath into and from a silicone urethra model under simulated clinical use conditions.
- Photobiological safety, Hawk controls the luminous flux of the light guide beam inside the endoscope to keep the actual illuminance of the endoscope at a level no higher than that of the predicated devices, thereby limiting photobiological safety.

Summary of optical performance specifications:

Items	Basic Parameters		
	Y6236 5H	Y6236 6H	TH3315 1
Field of view	90°	90°	62°
Direction of view	0°	0°	25°

The MTF50P Object space resolution(lp/mm) in the scope of depth of field of subject devices is shows as below. All endoscopes in this submission feature a wide depth-of-field design and are capable of providing clear focus across an observation distance range of 3–50 mm. In actual clinical use, the best working distance of TH3315 1 is around 10mm~20mm, and the best working distance of Y6236 5H and Y6236 6H is around 10mm~30mm，between this distance, subject endoscope can provide more than 3 lp/mm object space resolution.

MTF50P Object space resolution(lp/mm)

	Distance (mm)	5	10	15	20	25	30	35	40	45	50
TH3315 1	Center Field	8.0	7.9	8.0	7.5	6.5	5.6	4.6	4.3	3.8	3.4
	70% Field	9.9	12.1	9.9	7.2	5.4	4.2	3.2	2.9	2.5	2.2
Y6236 5H	Center Field	8.7	8.7	8.4	5.7	5.1	4.2	3.6	3.2	2.8	2.5
	70% Field	11.5	11.0	8.9	5.4	4.5	3.5	3.0	2.5	2.2	2.0
Y6236 6H	Center Field	14.2	9.1	6.3	4.4	3.9	3.1	2.5	2.3	2.1	1.9
	70% Field	16.1	8.4	5.4	3.6	3.1	2.5	1.9	1.8	1.7	1.5

Summary of the luminous transmittance by model,*τ_v is the photopically weighted luminous transmittance of the device, τ_e the radiant transmittance;*

Model	Mean τ_v (%)	Range of τ_v (%)	Mean τ_e (%)
TH3315 1	24.07	18.53 – 26.89	22.95
Y6236 5H	32.05	23.05 – 35.96	30.20
Y6236 6H	31.22	27.45 – 36.53	29.74

In addition to completing the comparative testing against the equivalent device, Hawk also completed the following studies to demonstrate that the proposed Cysto-Urethroscope and accessories meet the safety and performance requirements in clinical use.

4.2. Basic physical performance

- System sealing performance according to ISO 8600-7.
- Tensile Testing of Joints and Connections with 3.6kg weight.
- Ceramic Tip Mechanical Performance,ceramic tips were subjected to compressive failure testing tested.
- Water Resistance Performance of endoscope under 1 meter water for 12 hours.
- Luer connector performance according to ISO 80369-1 and ISO 80369-7.
- Irrigation and aspiration flow rate under simulated clinical use conditions.
- Surface and edges according to ISO 8600-1.
- Thermal safety, when connected to a Φ2.5mm light guide cable, the temperature at the endoscope tip will not exceed 41℃. However, if a light guide cable larger than Φ2.5mm is used and the endoscope operates in an air environment for an extended period, the tip temperature may exceed 41℃. Manufacturer uses structural design to keep the endoscope tip concealed within the sheath during operation, preventing contact with the patient to mitigate the risk of thermal injury.

4.3. Compatibility testing

Hawk has verified the compatibility of the equipment should be used together with subject devices recommended in Instruction of use.

4.4. Reprocessing validation

Hawk has completed the reprocessing validation based on the recommended reprocess method in Instruction for Use according to following standard of guideline:

- ANSI/AAMI ST98:2022
- AAMI TIR 12:2020/(R) 2023
- AAMI TIR 30:2011
- ISO 17664-1:2021
- ISO 17665:2024

In additional,the Repeat Reprocessing Cycle Life Verification also has been studied based on the reprocess method specified in the Instruction for Use.

4.5. Biocompatibility testing

Hawk has performed specific biocompatibility tests conducted in accordance with ISO 10993-1with finish products.

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic
- Pyrogenicity

4.6. Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

5. Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

6. Conclusion

Based on the non-clinical performance testing conducted, the subject Cysto-Urethroscopes and accessories are as safe and effective as the legally marketed predicate device (K041610). The performance testing data provided support a determination of substantial equivalence.