January 29, 2026

Hangzhou Hawk Optical Electronic Instruments Co., Ltd
Yayan Ding
Person Responsible for Regulatory Compliance
No.9 Xinda Road, Suoqian, Xiaoshan
Hangzhou, Zhejiang 311201
China

Re: K251923
Trade/Device Name: Medical Shaver System (Morcellator) (YSB-IIIA)
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: GCJ
Dated: December 22, 2025
Received: December 22, 2025

Dear Yayan Ding:

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
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251923

Device Name
Medical Shaver System (Morcellator) (YSB-IIIA)

Indications for Use *(Describe)*
It is intended for use under endoscopic visualization for the morcellation and removal of dissected benign prostatic hyperplasia (BPH) tissue during endoscopic surgical procedures in urology.

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.

510(k) Summary

In accordance with 21 CFR 807.92 the following summary information is provided:

Date Prepared: January 8, 2026
Manufacturer: Hangzhou Hawk Optical Electronic Instruments Co., Ltd
No.9 Xinda Road, Suoqian, Xiaoshan, Hangzhou,
Zhejiang 311201 P.R. China

Contact Person: Yayan DING
Person Responsible for Regulatory Compliance
Hangzhou Hawk Optical Electronic Instruments Co., Ltd
Tel: (+86) 0571-22811660
Email:christina.ding@chinahawk.cn

Identification of the Device:

Proprietary/Trade Name: Medical Shaver System (Morcellator) YSB-IIIA
Regulation Name: Endoscope and Accessories
Regulatory Number: 21 CFR 876.1500
Classification Product Code: GCJ
Device Class: Class II
Review Panel: General & Plastic Surgery

Predicate Device:

Proprietary/Trade Name: Cyber Blade
Regulation Name: Endoscope and accessories
Regulatory Number: 21 CFR 876.1500
Product Code: GCJ
Device Class: Class II
Review Panel: General & Plastic Surgery
Submitter/510(k) Holder: SIDAM s.r.l.
Clearance: K192499 (cleared July 31, 2020)

Device Description:

The device includes a control unit, handpiece, footswitch, blades, waste bottle, collection bottle, and suction tube. The device is a reusable morcellation device which is intended for use under endoscopic visualization for the morcellation and removal of dissected benign prostatic hyperplasia (BPH) tissue during endoscopic surgical procedures.

Principle of operation: Morcellation through the cutting effect of the cutting window, produced by the relative movement of the internal tube and the external tube.

Indications for Use:
It is intended for use under endoscopic visualization for the morcellation and removal of dissected benign prostatic hyperplasia (BPH) tissue during endoscopic surgical procedures in urology.

Comparison with Predicate Device:
The Medical Shaver System (Morcellator) YSB-IIIA and its predicate device, the SIDAM s.r.l. Cyber Blade (K192499), have the same intended use, and similar technological characteristics.

	Subject Device Medical Shaver System (Morcellator) YSB-IIIA	Predicate Device Cyber Blade (K192499)
Manufacturer	Hangzhou Hawk Optical Electronic Instruments Co., Ltd.	Sidam S.r.l
Trade Name	Medical Shaver System (Morcellator) YSB-IIIA	Cyber Blade
Product Code	GCJ	GCJ
Regulation Number	21 CFR 876.1500	21 CFR 876.1500
Regulation Name	Endoscope and accessories.	Endoscope and accessories.
Indications for use	It is intended for use under endoscopic visualization for the morcellation and removal of dissected benign prostatic hyperplasia (BPH) tissue during endoscopic surgical procedures in urology.	Cyber BLADE is intended for use under endoscopic visualization for the morcellation and removal of dissected benign prostatic hyperplasia (BPH) tissue during endoscopic surgical procedures in urology.
Users	Health care professionals	Health care professionals
Principle of operation	Morcellation through the cutting effect of the cutting window, produced by the relative movement of the internal tube and the external tube.	Morcellation through the cutting effect of the cutting window, produced by the relative movement of the internal tube and the external tube.

	Subject Device Medical Shaver System (Morcellator) YSB-IIIA	Predicate Device Cyber Blade (K192499)
Vacuum intensity regulation	Possible from the vacuum generator	Possible through the leverage on the morcellator
Speed regulation	Possible from the vacuum generator	Possible through the button on the morcellator
Blade dimension (external tube)	40 cm working length 0.45 cm external diameter (N5912) 0.48 cm external diameter (N5911A)	38 cm working length 0.47 cm external diameter
Maximum morcellation velocity	About 10 grams per minute (blade N5912, Bovine Heart) About 20 grams per minute (blade N5911A, Bovine Heart)	About 17 grams per minute
Suction flow rate (Range and adjusted)	≥1.5L/min	About 1.61 L/min
Rotational speed (tied to morcellation rate)	300-1600 R/min	500 - 1475RPM
Blade detachment (tensile strength)	Blade and handpiece are unlikely to detach due to force	Blade and handpiece are unlikely to detach due to force
Materials in contact with the tissue	Stainless steel	Stainless steel
Power supply	AC power supplied	The morcellator is battery powered. The battery charger is AC power supplied.
Suction pump	Part of the system	Not part of the system, must use an external suction system.
Vacuum extractor	≤ 0.08MPa	/

	Subject Device Medical Shaver System (Morcellator) YSB-IIIA	Predicate Device Cyber Blade (K192499)
Vacuum extractor flow	≥ 1.5L / min	/
Supplied Sterile	No	Yes
Re-usable	Reusable – blade and internal motor	The internal motor is reusable, but it never comes in contact with the patient.

Technology:
The Medical Shaver System (Morcellator) YSB-IIIA employs the same fundamental scientific technology as the predicate device.

Determination of substantial equivalence:

The Proposed Medical Shaver System (Morcellator) YSB-IIIA is substantially equivalent to the predicate SIDAM s.r.l. Cyber Blade (K192499) with regards to indication for use, performance capabilities, and technological characteristics.

The following is an overview of the differences between the proposed subject device Medical Shaver System (Morcellator) YSB-IIIA and the predicate Cyber Blade (K192499):

Note 1 Vacuum intensity regulation, Speed regulation

Both proposed device and predicate device have functions of vacuum intensity regulation and speed regulation. The vacuum intensity regulation and speed regulation of proposed device is possible from the vacuum generator and on the morcellator. The predicate device is only through the button on the morcellator. These functions were verified via testing.

Note 2 Blade dimension (external tube)

The proposed device dimension is 40 cm working length, 0.45 cm (N5912), and 0.48cm (N5911A) external diameter. The predicate device's dimension is 38 cm working length and 0.47 cm external diameter. They are close and in same range. They can demonstrate substantial equivalence with predicate device.

Note 3 Morcellation velocity

The proposed device morcellation velocity is about 10 and 20 grams per minute for N5912 and N5911A, the predicate device's morcellation velocity is about 17 grams per minute. The subject device contains a similar morcellation rate that is within range of the predicate device. The surgeons can select the appropriate blade according to morcellation velocity for patient condition. The Morcellation velocity performance was verified in bench test.

Note 4 Suction flow rate

They are close and in same range. They can demonstrate substantial equivalence with predicate device.

Note 5 Rotational speed

They are close and in same range. They can demonstrate substantial equivalence with predicate device.

Note 6 Patient Contact Materials

The patient contact materials are equivalent to the predicate device, both the subject and predicate device blade material meet ISO 10993-1 and FDA guidance requirement.

Note 7 Power supply

The proposed device's power supply is by AC power, while the predicate device morcellator is battery powered and the battery charger is AC powered. Both devices meet IEC60601-1 and IEC60601-1-2 safety and EMC requirement.

Note 8 Suction pump

Suction pump is part of the proposed device. FDA cleared suction systems are intended to be used with the predicate device. The predicate device refers to the Morce Scope Set 8970 (K041610), Richard Wolf Medical Instruments Corp. Suction pump performance was compared and verified through testing.

	Subject Device Medical Shaver System (Morcellator) YSB-IIIA	Device Morce Scope Set 8970 (K041610)	Comparison to Predicate
Manufacturer	Hangzhou Hawk Optical Electronic Instruments Co., Ltd.	Richard Wolf Medical Instruments Corp.	NA

Trade Name	Medical Shaver System (Morcellator) YSB-IIIA	Morce Scope Set 8970	NA
Intended use	It is used for aspirating irrigation fluid	The SUCTION PUMP is used for aspirating irrigation fluid in conjunction with a resectoscope or a morcellator following laser TURP.	Same.
Physical description	AC power, Microprocessor, pressure control	AC power, Microprocessor, pressure control	Same
Vacuum extractor	≤ -0.08Mpa	-0.06MPa~-0.01MPa	Equivalent Close and Better than predicate device.
Vacuum extractor flow	≥ 1.5L / min(liquid)	Aspiration: 1.4L/min	Equivalent Close and Better than predicate device.

Note 9 Supplied Sterile/Re-usable

The proposed device is supplied non-sterile, and the device is intended to be sterilized prior to usage. Sterilization and cleaning validation were conducted and verified. The predicate morcellator is single use only. Its internal motor is reusable, but it never comes in contact with the patient. Normally a single use device raises less concerns than a re-usable one. However, the proposed device's reprocessing methods and instructions were verified. The reprocessing validation meet the sterilized assurance level.

Summary of Non-clinical test:

The Medical Shaver System (Morcellator) YSB-IIIA conducted performance bench testing.

The device was evaluated for biocompatibility, cleaning and sterilization effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to comply with applicable medical device safety standard, The Medical Shaver System (Morcellator) YSB-IIIA complies with voluntary standards:

- IEC60601-1 Edition 3.2 2020-08 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 &

A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]

- IEC 60601-2-18-2009 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC /TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366-1 Edition 1.1 2020-06 Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
- ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- 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 Part 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 — Part 23: Tests for irritation
- ISO 15223-1 Fourth edition 2021-07 Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements
- ISO 20417: 2021 Medical devices - Information to be supplied by the manufacturer
- ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices
- ISO 8600-1 Fourth Edition 2015-10-15 Endoscopes - Medical endoscopes and endotherapy devices -- Part 1: General requirements
- ISO 17664-1:2021 Processing of health care products — Information to be

provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

- AAMI TIR12:2020/(R)2023 Designing testing and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers
- ISO 17665:2024 Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices

Summary of Clinical Tests:
The subject of this premarket submission did not require clinical studies to support substantial equivalence.

Conclusion:
Hangzhou Hawk Optical Electronic Instruments Co., Ltd considers the Medical Shaver System (Morcellator) YSB-IIIA to be substantially equivalent, with respect to safety and effectiveness to the predicate device.