August 18, 2026

Axora Medical, Inc.
% Natalie J. Kennel
Regulatory Affairs Consultant
NJK & Associates, Inc.
13721 Via Tres Vista
San Diego, CA 92129

Re: K260984
Trade/Device Name: HERizon RD5™ Resecting Device
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: II
Product Code: HIH
Dated: July 22, 2026
Received: July 23, 2026

Dear Natalie J. Kennel:

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 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,

Reginald K. Avery -S

for Jason R. Roberts, Ph.D.
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.	K260984

Please provide the device trade name(s).

HERizon RD5™ Resecting Device

Please provide your Indications for Use below.

The HERizon RD5™ Resecting Device is intended for intrauterine use by physicians trained in hysteroscopy to resect and remove tissue such as endometrial polyps.

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

Sponsor: Axora Medical Inc.
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Jacksonville, FL 32202

Contact Person: Ms. Natalie J. Kennel
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Date Prepared: August 16, 2026

DEVICE INFORMATION:

Proprietary Name: HERizon RD5™ Resecting Device
Regulation Name: Hysteroscope and accessories
Classification: Class II
Product Codes: HIH
Regulations: 21 CFR 884.1690
Classification Panel: Obstetrics/Gynecology

PREDICATE DEVICES:

Table 1 contains information about the predicate devices:

Table 1 Predicate Device Information

510(k)#	Product Name	Sponsor /510(k) holder	Clearance Date	Role
K233500	Benesta™ Tissue Removal	Caldera Medical	Nov. 30, 2023	Primary predicate
K191538	Resectr™ Device	Boston Scientific/ Minerva Surgical/ Axora Medical[1]	Jan.16, 2020	Secondary predicate

None of the predicate devices have been the subject of a design related recall.

[1] Boston Scientific Corporation obtained the clearance and later sold this clearance to Minerva Surgical. Axora Medical acquired this asset from Minerva on Jan. 30, 2026

PRODUCT DESCRIPTION:

The HERizon RD5™ Resecting Device is a battery powered, motor driven, and manually actuated hysteroscopic surgical instrument used to resect and remove tissue under direct visualization. The device is supplied sterile for single use only. The device is offered in a 5Fr size for compatibility with hysteroscopes that can accommodate instruments with a 1.65 mm outer diameter or larger. The device can be used with any fluid management system made with standard luer and/or stepped connectors.

The HERizon RD5™ device consists of a distal and proximal section. The distal section is comprised of an outer cannula with an open Resecting Window at the distal end, and a cutting element that rotates within the lumen of the outer cannula to resect tissue within the Resecting Window. The proximal section, made of molded plastics, is comprised of a cylindrically shaped handle with an Activation Button. Depressing the Activation Button actuates a motor that spins a blade within the Resecting Window to resect and remove target tissue. Depressing the Activation Button also opens a mechanical valve within the handle body. When open, evacuation of resected tissue is enabled. The devices are provided assembled with a vacuum tube port for use with a suction source. As tissue is resected, it is evacuated through the length of the device and out the vacuum tube port. The distal section, the patient contacting portion, including the cannula and cutting element are made of stainless steel.

INDICATIONS FOR USE:

The *HER*izon RD5™ Resecting Device is intended for intrauterine use by physicians trained in hysteroscopy to resect and remove tissue such as endometrial polyps.

SUBSTANTIAL EQUIVALENCE

Table 2 contains the substantial equivalence table comparing the HERizon RD5™ Resecting Device to its predicates .The table shows that the subject device has the same intended use as both predicates. The subject device uses similar design and technology as one or both of the predicates. The subject device is battery powered, same as its primary predicate device. The subject device is a single use disposable device provided sterile, same as both predicates. The subject device has similar dimensions and compatibility as at least one model of both predicates. The subject device is made of the same type of materials as both predicates. The subject device has some minor differences in the way the resection is activated in the predicates but the differences do not raise different issues of safety and effectiveness.

The HERizon RD5™ Resecting Device has the same intended use and similar technology characteristics as compared to its primary and secondary predicate devices. The difference between the subject device and predicate devices do not raise different questions of safety or effectiveness.

Table 2 Substantial Equivalence Table Comparing HERizon RD5™ Resecting Device to its Predicates

Characteristic	Subject Device	Primary Predicate	Secondary Predicate	Comparison
Trade Name	HERizon RD5™ Resecting Device	Benesta® Tissue Removal Device	Resectr™ Tissue Resection Device	NA
510(k)	New	K233500	K191538	NA
Submitter/ 510(k) Holder	Axora Medical Inc.	Caldera Medical Inc.	Minerva Surgical/Axora Medical[2]	NA
Device type	Hysteroscope and accessories	Hysteroscope and accessories	Hysteroscope and accessories	Same
Classification	Class II	Class II	Class II	Same
Regulation	884.1690	884.1690	884.1690	Same
Product code	HIH	HIH	HIH	Same
Indications for Use	The *HER*izon RD5™ Resecting Device is intended for intrauterine use by physicians trained in hysteroscopy to resect and remove tissue such as: endometrial polyps	The Caldera Medical Benesta™ Tissue Removal Device is intended for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as: submucous myomas, endometrial polyps, and retained products of conception.	The Resectr™ Tissue Resection Device is intended for intrauterine use by physicians trained in hysteroscopy to resect and remove tissue, including focal lesions such as endometrial polyps.	Same intended use to resect and remove intrauterine tissue. The indications included are in both primary and secondary predicate
Usage	Single use disposable	Single use disposable	Single use disposable	Same
Use Environment	operating room, surgical center and physician's office environments where surgical procedures are performed	operating room, surgical center and physician's office environments where surgical procedures are performed	operating room, surgical center and physician's office environments where surgical procedures are performed	Same
Power source/ Operating voltage	Battery/ Up to 6 V	Battery/ 7.7 - 9.0 V	Manual	Primary predicate is battery powered with similar voltage. Slight difference in voltage does not raise different issues of safety or effectiveness.

[2] Boston Scientific Corporation obtained the clearance and later sold this clearance to Minerva Surgical. Axora Medical acquired this asset from Minerva on Jan. 30, 2026.

Characteristic	Subject Device	Primary Predicate	Secondary Predicate	Comparison
Sterilization	Provided sterile- Ethylene oxide	Provided sterile- Ethylene oxide	Provided sterile- Ethylene oxide	Same
Outer diameter	5F (1.65 mm)	Benesta OD 4.0 mm (12F)	5F (1.65 mm) and 9F (3.0mm)	Subject device same as one of two Resectr™ predicate device models (5F)
Cannula length	36.3 cm	35 cm	35.3 cm	Subject device similar to both predicates
Resecting Window length	5.0 mm	15.0 mm	5.0 mm (5 F)	Subject device same as Resectr™ predicate
Directionality of resecting blade	Resecting blade oscillates radially relative to the cannula	Resecting blade translates axially along the cannula length. During translation, resecting blade rotates	Resecting blade oscillates radially relative to the cannula	Subject device same as Resectr™ predicate
Resecting Window orientation	Side facing window	Side facing window	Side facing window	Same
Resecting Window orientation indicator	Laser markings	Laser markings	Laser markings	Same
Blade actuation	Upon pressing a button, a motor is activated that rotates the resection blade. The resection blade rotates three times in one direction before changing directions and rotating three times in the opposite direction.	Blade is actuated using a momentary switch to activate the motor. An additional sliding switch sets the on/off state of the device which connects or disconnects the internal battery to the rest of the internal electronics.	Each handle squeeze and release on the Resectr™ device rotates the blade bi-directionally for a total of six resection actions across the cannula window.	Subject device is similar to the predicate devices. Primary predicate blade is actuated with a switch or motor like subject device. Secondary predicate is actuated with manual squeeze. Differences are minor and do not raise different issues of safety or effectiveness
Blade material/ Patient contact & duration	Stainless Steel / Externally communicating, limited duration (< 24 hours)	Stainless Steel / Externally communicating, limited duration (< 24 hours)	Stainless Steel/ Externally communicating, limited duration (< 24 hours)	Subject device material, patient contact and duration is same as both predicates
Vacuum and tissue collection	HERizon RD5™ Resecting Device is connected to an external suction source and tissue catch.	Benesta™ device is connected to an external suction source and tissue catch.	Resectr™ Device is connected to an external suction source and tissue catch.	Same
Supplied accessories	None	None	None	Same

Characteristic	Subject Device	Primary Predicate	Secondary Predicate	Comparison
Compatibility	Hysteroscopes with a working channel of 1.65 mm or larger	Hysteroscopes with a working channel of 4.0 mm (12F)	Hysteroscopes with a working channel of 1.65 mm or larger (5F) or 3.0 mm or larger (9F)	Subject device is same as one of two Resectr™ predicate device models.
Bench testing	Range of mechanical, functional, and performance testing	Unknown	Range of mechanical, functional, and performance testing	Subject device was subjected to the same or similar bench testing as Resectr™ predicate device. Bench testing of primary predicate is unknown due to 510(k) statement

NON-CLINICAL PERFORMANCE DATA

Biocompatibility

Biocompatibility studies were performed in accordance with the 2023 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" and ISO 10993-1:2018 as follows for a device where the distal portion of the device has patient contact that is externally communicating with a limited duration of less than 24 hours:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2021
- Vaginal irritation (ISO 10993-23:2021)
- Acute systemic toxicity (ISO 10993-11:2017)
- Material mediated pyrogenicity (ISO 10993-11:2017, USP<151> 2017)

Sterilization

The HERizon RD5™ Resecting Device is packaged for single use and terminally sterilized with Ethylene Oxide (EO). EO sterilization validation was performed per ISO 11135:2014/AMD 1:20218 'Sterilization of health care products – Ethylene oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices – Amendment 1: Revision of Annex E Single batch release.' EO residuals were confirmed to be within ISO 10993-7:2008/AMD 1:2019 'Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.'.

Package Integrity

Sterile barrier/packaging validation was performed following simulated shipping and handling per ASTM D4169 -23e1 'Standard Practice for Performance Testing of Shipping Containers and Systems' and related standards as follows:

- Visual seal inspection (ASTM F1886/F18886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F1929-23 Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- Pouch Seal Peel Strength Testing (ASTM F88/F88M-21 'Standard Test Method for Seal Strength of Flexible Barrier Materials'

Electrical Safety/EMC

The battery powered HERizon RD5™ Resecting Device was tested and found to conform to the following electrical safety and EMC standards:

Electrical safety (IEC 60601-1 Edition 3.2 2020-08 'Consolidated Version: Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance'.

IEC 60086-5 Primary Batteries – Part 5 with Aqueous Electrolytes
EMC (IEC 60601-1-2:2014/AMD1:2020)

Mechanical/Functional Performance/Shelf-Life Testing

Mechanical and functional performance testing was conducted on samples at baseline T = 0 and aged T = 1 year accelerated aging (per ASTM F1980). The performance tests completed to demonstrate that the HERizon RD5™ Resecting Device functions as intended include:

- Cutting/Resection Performance
- Device/Scope Compatibility
- Dimensional Measurements
- Durability
- Functionality of Activation Button
- Outer Tube (Cannula) Rotation
- Vacuum Maintenance
- Torque strength testing
- Tensile testing

All test results met the predefined acceptance criteria.

CLINICAL STUDIES

No clinical studies were performed.

CONCLUSION

The results of the above-described performance testing demonstrate that the HERizon RD5™ Resecting Device is as safe and effective as the predicate devices and supports a determination of substantial equivalence.