October 1, 2021

PENTAX of America, Inc.
William Goeller
Vice President, Quality Assurance and Regulatory Affairs
3 Paragon Drive
Montvale, NJ 07645-1782

Re: K212201
Trade/Device Name: PENTAX Medical Auto Leakage Tester SHA-P6
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: PCV
Dated: July 12, 2021
Received: July 14, 2021

Dear William Goeller:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212201

Device Name
PENTAX Medical Auto Leakage Tester SHA-P6

Indications for Use *(Describe)*
The PENTAX Medical Auto Leakage Tester SHA-P6 is intended to be used to perform leakage testing on PENTAX Medical flexible endoscopes.

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

a. Applicant

PENTAX of America, Inc.
3 Paragon Drive
Montvale, New Jersey 07645-1782

b. Contact/Application Correspondent

William Goeller
Vice President, Quality and Regulatory Affairs
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Phone: 201-571-2300 ext. 2318
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Email: william.goeller@pentaxmedical.com

c. Date Prepared: November 20, 2020

d. Common Name: Leak Tester

e. Name of the System: PENTAX Medical Auto Leakage Tester SHA-P6

f. Regulation Number: 21 CFR Part 876.1500

g. Regulation Name: Endoscope and accessories

h. Regulatory Class: Class II

i. Product Code: PCV

j. Predicate Device: Automated Endoscope Leak Tester ALT-Y0003 (K123704)

k. Reference Device: ZUTRON Medical Endoscope Leak Tester, Model ZUTR-10003 (K093718)

l. Device Description:

PENTAX Medical Auto Leakage Tester SHA-P6 (Hereinafter "the Device") is intended to be used to perform leakage testing on PENTAX Medical flexible endoscopes. Endoscopes are complex devices that consist of various mechanical, optical, and video elements that might be affected by exposure to fluid. Therefore, endoscope leak testing is a crucial procedure for the proper endoscope cleaning and disinfecting process. The Device is designed to detect leaks by measuring the difference in air pressure over time using the Automated Leak Test mode (ALT

mode). The Device conducts two types of tests: a dry leakage test and a wet leakage test. The dry leakage test is performed when the device feeds air into the endoscope until a set pressure is reached, and then monitors the pressure over a specific period of time. The wet leakage test is conducted after confirming the absence of a leak during the dry leakage test, by immersing the endoscope in potable water to test for loss of integrity in its watertight construction. The Device is compatible with PENTAX Medical flexible endoscopes.

m. Statement of Indications for Use

The PENTAX Medical Auto Leakage Tester SHA-P6 is intended to be used to perform leakage testing on PENTAX Medical flexible endoscopes.

n. Statement of Substantial Equivalence

The Device is substantially equivalent to the predicate Automated Endoscope Leak Tester ALT-Y0003 (K123704) (Hereinafter "the Predicate Device"). Both devices are used for leak testing of flexible endoscopes in combination with a connecting tube feeding air into the endoscope.

The two devices are substantially equivalent and have:

- similar Intended Use
- use the same Operating Principle
- incorporate the same Basic System Design

The main differences are:

- The Device only has an Automated Leak Test mode (ALT) for determining the watertight integrity of the endoscope.
- The Predicate Device has and Automated Leak Test mode (ALT) and A Manual Leak Test mode (MLT).
- The predicate device has additional features such as RFID tracking and internal memory to store test results. The Device does not have these additional features.

o. Comparison Table

Table 7.1 Comparison of features between the Device and the Predicate Device

Item		Predicate Device	Reference Device	The Device	Remark
Product Name		Automated Endoscope Leak Tester	ZUTRON Medical Endoscope Leak Tester	PENTAX Medical Auto Leakage Tester	-
Model Number		ALT-Y0003	ZUTR-10003	SHA-P6	-
510(k) Number		K123704	K093718	N/A	-
Intended Use		This equipment is intended to be used to perform and record leakage testing on Olympus flexible endoscopes.	The Zutron Medical ZUTR-10003 Endoscope Leak Tester is designed to detect interior and exterior leaks in endoscopes	This product is intended to be used to perform leakage testing on PENTAX Medical flexible endoscopes.	Similar *1
AC adapter	DC output voltage/current	45 VA	12V, 3.3A	7.5 V, 1.6 A	Similar
	AC input frequency	50/60 Hz	50/60 Hz	50/60 Hz	Identical
	AC input voltage	100 - 120 V	100 - 240 V	100 - 240 V	Similar
Built - in packaged lithium battery	Battery capacity	N/A	N/A	2,600 mAh	Different *2
Size		280 mm (W) x 201 mm (H) x 184 mm (D) 11.0 in (W) x 7.9 in (H) x 7.2 in (D)	127 mm (W) x 88.9 mm (H) x 196.85 mm (D) 5.00 in (W) x 3.5 in (H) x 7.75 in (D	154 mm (W) x 63.2 mm (H) x 95.6 mm (D) 6.06 in (W) x2.49 in (H) x 3.76 in (D)	Similar
Weight		5.5 kg (12.1 lbs.)	1.4 kg (3.10 lbs.) (main unit only)	380 g (0.84 lbs.) (main unit only)	Different *3

Item	Predicate Device	Reference Device	The Device	Remark
Automated Leakage Testing (ALT)	Yes	Yes	Yes	Identical
Manual Leakage Testing (MLT)	Yes	No	No	Different *4

The following are explanations regarding the differences between the subject and predicate devices:

*1 Intended use

Intended use of the Device is similar to the Predicate Device regarding leakage testing for the flexible endoscopes.

*2 Built - in packaged lithium battery

The availability of the built - in packaged lithium battery is a minor addition and does not raise and safety and effectiveness concerns.

*3 Weight

This is due to the difference of mechanical constructions, which does not raise any safety and effectiveness concerns.

*4 Manual Leakage Testing (MLT)

The Device only has an Automated Leakage Testing (ALT) mode. The availability of the Manual Leakage Testing (MLT) in the Predicate Device is a minor functional difference and does not raise and safety and effectiveness concerns.

Comparison to the Reference device:

ZUTRON Medical Endoscope Leak Tester, ZUTR-10003 (K093718) was selected as a Reference device due to the fact that it was used as one of the predicate devices for the premarket notification application of the Automated Endoscope Leak Tester ALT-Y0003 (K123704), which is the Predicate Device under this premarket notification application of the Device.

The Reference device, ZUTRON Medical Endoscope Leak Tester, ZUTR-10003 (K093718) has been used for leakage detection testing, where both subject and predicate devices were compared in their ability to find leakage within compatible endoscopes. Subject device has been found to be substantially equivalent to the Reference device in its ability to detect leaks.

p. Software

Software verification and validation tests 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. See Section 19 Software for details.

Cybersecurity risks have been assessed according to the FDA Guidance for Industry and Staff "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" issued October 2, 2014. No cyber security risks have been detected since the Device has no other interface than an air feeding tube to an endoscope tested.

q. EMC and Electrical Safety

The acceptable level of electromagnetic compatibility (EMC) and electrical safety (ES) for the Device were confirmed by the following standards:

IEC 60601-1-2:2014; IEC 60601- 1:2005+CORR 1:2006+CORR 2:2007+A1:2012

r. Performance Testing

The verification test was conducted to confirm that the leak detection capabilities of the Device were similar to the Predicate Device. The Endoscope Leak Tester ZUTR-10003 (K093718) was used the comparison device, which was the device used for leak detection for the Predicate Device. The Device was successfully tested for all functions, performance, and safety as per FDA Guidance and recognized consensus standards.

s. Conclusion

After analyzing the intended use, technological characteristics (including operating principle, performance characteristics and constituent materials), and labeling, the Device did not raise any issue regarding safety and effectiveness. Accordingly, the testing concluded that the Device is substantially equivalent to the Predicate Device and the Reference Device.