December 1, 2023

PENTAX of America, Inc.
Gurvinder Singh Nanda
Senior Director, Regulatory Affairs and Quality
3 Paragon Drive
Montvale, New Jersey 07645-1782

Re: K232249
Trade/Device Name: PENTAX Medical Gas/Water Feeding Valve OE-B14
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODC, OCX
Dated: July 27, 2023
Received: July 28, 2023

Dear Gurvinder Singh Nanda:

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.

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,

Sivakami Venkatachalam -S

*for*
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)*
K232249

Device Name
PENTAX Medical Gas/Water Feeding Valve OE-B14

Indications for Use *(Describe)*
The Gas/Water Feeding Valve OE-B14 is intended to be attached in place of Air/Water Feeding Valve (OE-B12) to PENTAX Medical GI endoscopes and used to feed the gas/water to the body (via the air/water channel).

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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K232249

**PENTAX Medical Gas/Water Feeding Valve OE-B14**
**Traditional 510(k) Submission**

# 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 221 CFR 807.92. All data included in this document is accurate and complete to the best of PENTAX Medical's knowledge.

## 1. SUBMITTER

**Applicant:** PENTAX Medical
HOYA Corporation PENTAX Division
3 Paragon Drive
Montvale, New Jersey 07645-1782

**Contact:** Gurvinder Singh Nanda
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**Date Prepared:** Nov 27th, 2023

## 2. SUBJECT DEVICE

PENTAX Medical is seeking clearance of a new product of PENTAX Medical Gas/Water Feeding Valve OE-B14 with the compatible PENTAX Medical Video Upper GI Gastroscope EG29-i20c and PENTAX Medical Video Colonoscope EC38-i20cL.This PENTAX Medical Gas/Water Feeding Valve OE-B14 is an accessory and is part of the Pentax Medical EPK-i8020c Video Imaging System (K231249).

| | | |
|---|---|---|
| Device Name | PENTAX Medical Gas/Water Feeding Valve OE-B14 | |
| Common Name | Endoscope Channel Accessory | Endoscopic Irrigation/Suction System |
| Classification Name | Endoscope and accessories | |
| Regulation No. | 876.1500 | |
| Device Class | II | |
| Product Code | ODC | OCX |
| Classification Panel | Gastroenterology / Urology | |

## 3. PREDICATE DEVICE

The predicate device for this submission is PENTAX Gas/Water Feeding Valve OF-B194 which is compatible with PENTAX Medical Video Upper GI Scope EG29-i10c and PENTAX Medical Video Colonoscope EC34-i10cL (K190805).

| Subject Device | Predicate Device |
|---|---|
| PENTAX Medical Gas/Water Feeding Valve<br>OE-B14<br><br>PENTAX Medical Video Processor<br>EPK-i8020c (K231249) | PENTAX Medical Gas/Water Feeding Valve<br>OF-B194 (K190805)<br><br>PENTAX Medical EPK-i7010 Video Processor (K150618) |
| PENTAX Medical Video Upper GI Scope<br>EG29-i20c (K231249) | PENTAX Medical Video Upper G.I. Scope<br>EG29-i10 (K131902) |
| PENTAX Medical Video Colonoscope<br>EC38-i20cL (K231249) | PENTAX Medical Video Colonoscope<br>EC38-i10L (K131855) |

## 4. DEVICE DESCRIPTION

**PENTAX Medical Gas/Water Feeding Valve OE-B14**

The Gas/Water Feeding Valve OE-B14 is intended to be attached in place of Air/Water Feeding Valve (OE-B12) to PENTAX Medical GI endoscopes and used to feed the gas/water to the body (via the air/water channel).

The OE-B14 is attached onto the air/water feeding cylinder of the control body of PENTAX Medical endoscope. The endoscope is linked to non-flammable gas cylinder and the water bottle assembly via air/water feeding circuit.

The device descriptions for the PENTAX Medical EPK-i8020c Video Imaging System remain unchanged from K231249. They include the PENTAX Medical Video Processor EPK-i8020c, PENTAX Medical Video Upper GI Scope EG29-i20c, and PENTAX Medical Video Colonoscope EC38-i20cL.

## 5. INTENDED USE AND INDICATIONS FOR USE

**Intended use and Indications for use for PENTAX Medical Gas/Water Feeding Valve OE-B14**

The Gas/Water Feeding Valve OE-B14 is intended to be attached in place of Air/Water Feeding Valve (OE-B12) to PENTAX Medical GI endoscopes and used to feed the gas/water to the body (via the air/water channel).

## 6. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

The subject device OE-B14 is technologically and functionally equivalent to the predicate device OF-B194, and the difference between the two devices are the compatible endoscopes.

The changes in the subject device have been evaluated through performance testing including air tightness and gas / water feeding volume and raised no issues of safety and effectiveness of the device. These differences have no effect on the performance, function or general intended use of the device.

## 7. NON-CLINICAL PERFORMANCE DATA

The PENTAX Medical Gas/Water Feeding Valve OE-B14 has been successfully tested for their functions, performance, and safety as per FDA recognized consensus standards. The following performance data are provided in support of the substantial equivalence determination.

i. Reprocessing Validation

The PENTAX Medical Gas/Water Feeding Valve OE-B14 is a reusable semi-critical device (Spaulding Classification System). Since it is packaged non-sterile, it must be properly cleaned and sterilized before use.

As result of the assessment, simulated use testing, cleaning, high-level disinfecting and rinsing (after cleaning and after HLD) validation studies of the OE-B14 were conducted and confirmed the effectiveness of reprocessing procedures in accordance with FDA's 2015 Final Guidance, *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."* Acceptance criteria were established in accordance with AAMI TIR 30: 2011/(R)2016 for amount of residual soil accumulation and extraction efficiency. All acceptance criteria were satisfied.

ii. Sterilization and Shelf Life

PENTAX Medical coordinated with Nelson Laboratories, LCC to validate the use of steam sterilization for the sterilization of the OE-B14. The device is not provided sterile, therefore, shelf-life is not applicable.

iii. Biocompatibility

Biocompatibility of the OE-B14 on the indirect contact materials was confirmed by assessing the cytotoxicity, sensitization, and intracutaneous reactivity in accordance with ISO 10993-1: 2018 "*Biological evaluation of medical devices"*. The risk levels of local toxicity were determined as "acceptable" as a result of applying the risk level of local toxicity to the risk evaluation criteria.

iv. Software and Cybersecurity

The PENTAX Medical Gas/Water Feeding Valve OE-B14 does not contain software. Therefore, no software testing was repeated.

v. Electrical Safety and Electromagnetic compatibility

The OE-B14 is not an electrical accessory. Therefore, no testing of electrical safety or electromagnetic compatibility testing were repeated.

vi. System Performance

The bench testing results of the OE-B14 demonstrated the performance enough to conduct the gas/water feeding procedure in a clinical use.

No optical characteristics bench testing or animal image capture study were conducted since the OE-B14 is not an optical accessory.

vii. Mechanical Performance

The mechanical performance of the PENTAX Medical Gas/Water Feeding Valve OE-B14 was verified by comparing it to the OF-B194 in combination with the PENTAX Medical Video Colonoscope EC38-i0cL (K190805).

**Substantial Equivalence Discussion:**

After analyzing the intended use, indications for use, technological characteristics (including fundamental operating principle, energy source, scientific technology, functional characteristics, design features, performance characteristics, and constituent materials), labeling, and sterilization method, PENTAX Medical concludes that the subject device is as safe and effective as the predicate device. There are no differences in indications for use and intended use between the subject and predicate device and are therefore substantially equivalent. The technological differences in terms of design features, performance characteristics and constituent materials are not substantive.

## 8. CONCLUSION

PENTAX Medical Gas/Water Feeding Valve OE-B14 with the compatible PENTAX Medical Video Upper GI Scope EG29-i20c and PENTAX Medical Video Colonoscope EC38-i20cL does not raise any different questions of safety and effectiveness.
Therefore, the subject device is substantially equivalent to the identified predicate, the PENTAX Gas/Water Feeding Valve OF-B194 with the compatible PENTAX Medical Video Upper GI Scope EG29-i10c and PENTAX Medical Video Colonoscope EC34-i10cL (K190805).