July 28, 2023

H&A Mui Enterprises Inc.
Tammy Mui
Operations Manager
145 Traders Blvd. E., Unit #34
Mississauga, Ontario L4Z 3L3
Canada

Re: K222587
Trade/Device Name: PatCom Distal Chip Endoscope
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: June 27, 2023
Received: June 28, 2023

Dear Tammy Mui:

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,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K222587

Device Name
PatCom Distal Chip Endoscope

Indications for Use *(Describe)*
The Patcom Distal Chip Endoscope is indicated when endoscopic visualization in the regions of mouth, nasal cavity, and upper airway is required.

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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Mui Scientific
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July 28, 2023

510(k) Summary

Summary prepared by:

Contact Person: **Tammy Mui**
Title: **Operations Manager**
Manufacturer: **H&A Mui Enterprises Inc., o/a Mui Scientific**
Address: **145 Traders Blvd. East, Unit #33-34, Mississauga, Ontario, Canada L4Z 3L3**
Phone: **(905) 890-5525**
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Email: **tammy.mui@muiscientific.com**

Trade name: **PatCom Distal Chip Endoscope**
Common name: **Nasopharyngoscope**
Classification name: **Nasopharyngoscope (flexible or rigid) (as per CFR 874.4760)**
Class: **2**
Review Panel: **Ear Nose & Throat**
Product Code: **EOB**

Predicate Device	510(k) Number	Manufacturer
Schoelly CMOS Video Nasopharyngoscope	**K132009**	**Schoelly Fiberoptic GmbH**

Note: An agreement exists between the following companies:
1. Zhongshan Wesee Meditech Co., Ltd (the actual manufacturer of the endoscopes)
2. H&A Mui Enterprises Inc, o/a Mui Scientific (the virtual manufacturer of the endoscopes for Canada, the United States, and the EU)
3. PatCom Medical Inc (the exclusive distributor for Canada and the United States only)

Indications for Use:

The Patcom Distal Chip Endoscope is indicated when endoscopic visualization in the regions of mouth, nasal cavity, and upper airway is required.

Intended Use:

The PatCom Distal Chip Endoscope is a video endoscope used for visualization to aid in diagnosis in the regions of mouth, nasal cavity, and upper airway.

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It is to be used only by healthcare professionals who have received adequate training in handling nasopharyngoscopes.

As the indicated location of use is not considered a sterile environment: sterility of these medical devices is not required

This device is for transient use (under 24 hrs), and will come in direct contact with the patient's mucosal lining.

Device Description:

The PatCom Distal Chip Endoscope is a portable video endoscope for visualization in the regions of the mouth, nasal cavity, and upper airway. It is made up of the grip section and insertion tube. It requires connection via USB to a laptop computer, and gains power from the USB ports which supplies 5V of electricity with a maximum current of 0.5A. This is sufficient to power the endoscope. The endoscope does not need an external CCU for image processing, as the processing is done directly on the device on a small chip. It converts the light and color information received by the image sensor into binary numbers (patterns of zeros and ones). The USB Video Class (UVC) driver is a Microsoft-provided AVStream minidriver that provides driver support for USB Video Class devices. When a device uses UVC, it does not need to support their own driver, but instead works automatically with the system-supplied driver. It is compatible to all Windows and Mac computers, with a simple plug and play feature. The visualization from the distal chip is projected onto the computer monitor, at a resolution of 720px1280p high definition.

The insertion tube portion of the device is used for visualization within the natural orifices of the mouth and the nasal cavities and in the upper airway anatomy. The light emitted by the LED light source at the distal end of the tip is illuminated into the body cavity of the subject, and the image is displayed onto a screen.
The grip section of the device contains a control knob for moving the distal end of the insertion tube bend up or down, up to 130 degrees in either direction.
The proximal end of the grip section contains the USB connector, for plug and play with a computer, for power and to provide visualization of the camera chip found at the distal end of the insertion tube.

The PatCom Distal Chip Endoscope is substantially equivalent to the Schoelly CMOS Video Nasopharyngoscope, manufactured by Schoelly Fiberoptic GmbH. The Schoelly Nasopharyngoscope has already been approved for the US market since 2014. Similar to the PatCom Distal Chip Endoscope, their nasopharyngoscope also has a grip section, insertion tube section, and a manual knob for angulation of the tip, and are both used for visualization and diagnosis within the nose, mouth and throat.
The Schoelly Nasopharyngoscope has been selected as an equivalent device based on a detailed comparison of intended use, technological, imaging and biological characteristics. The intended use of PatCom Distal Chip Endoscope was considered the same as the predicate device, but small differences were identified for structure and technological characteristics. Rationales have been provided to ensure that these differences do not raise any additional safety or performance risks of the PatCom Distal Chip Endoscope compared with equivalent

device. Data generated from performance studies undertaken has also been used for comparison and to substantiate that it is safe to extrapolate data from equivalent devices. The main difference between the submitted device and the predicate device is the power supply. The distal end of the grip section contains the USB connector, for plug and play with a laptop computer, for power and to provide visualization of the distal chip found at the end of the insertion tube. It requires connection via USB to a laptop computer, and gains power from the USB ports which supplies 5V of electricity with a maximum current of 0.5A. This is sufficient to power the endoscope. The device does not need an external CCU for image processing, as the processing is done directly on the device on a small chip. It converts the light and color information received by the image sensor into binary numbers (patterns of zeros and ones). The USB Video Class (UVC) driver is a Microsoft-provided AVStream minidriver that provides driver support for USB Video Class devices. When a device uses UVC, it does not need to support their own driver, but instead works automatically with the system-supplied driver. It is compatible to all Windows and Mac computers, with a simple plug and play feature. The visualization from the distal chip is projected onto the computer monitor, at a resolution of 720px1280p high definition. The predicate device, however, requires connection to a control unit for power, which in turn, is powered by connection to a 110V outlet.

Below is a comparison table of the PatCom Distal Chip Endoscope with the predicate device:

	Predicate Device	Subject Device
Trade name	Schoelly CMOS Video Nasopharyngoscope	PatCom Distal Chip Endoscope
510K holder	Schoelly Fiberoptic GmbH	Mui Scientific
510K number	K132009	K222587
Manufacturer	Schoelly Fiberoptic GmbH	Mui Scientific
Indications For Use	The Schoelly CMOS Video Nasopharyngoscope System may only be used by persons with an appropriate medical qualification and who are acquainted with the rhino/laryngoscopic technique. The endoscope is used for endoscopic diagnosis within the nasal lumens and airway anatomy, and is intended to provide visualization via a video monitor.	The Patcom Distal Chip Endoscope is indicated when endoscopic visualization in the regions of mouth, nasal cavity, and upper airway is required.
Environment of Use	Healthcare facility/hospital	Healthcare facility/hospital
Discussion	In comparing the Indication for Use of the predicate and the proposed device, we found they are general similar, but utilizing different terminology for the same physical anatomy structures (lumens/cavity, airway anatomy/upper airway). According to the description above, the clinical application of the Distal Chip Endoscope and the equivalent device are essentially identical and does not pose a significant issue of safety or efficacy.	
Technical Specifications		
Power Supply	Endoscope is powered by a	5V d.c., obtained from the USB connection

	control unit. The control unit is powered by standard 110V outlet via an IEC cable	with a laptop computer
Field of View angle	85°	110°
Direction of view	0°	0°
Depth of Field	6 – 60mm	6-60mm
Insertion Tube outer diameter (mm)	3.8mm	3.2mm
Instrument Channel	No channel	No channel
Configuration	Light-Emitting (LED), Endoscope UP/DOWN angulation control knob, Bending section	Light-Emitting (LED), Endoscope UP/DOWN angulation control knob, Bending section
Working length	300mm	340mm
Angulation range	UP130° Down130°	UP130° Down130°
Source of examination light	LED	LED
Software	Unknown level of concern (possibly low); image processing done on external control unit; proprietary driver required	Low level of concern; image processing done on internal chip in endoscope; standard USB Video Class (UVC) driver
Discussion	The biggest difference between the proposed and predicate device exists in the aspect of power supply. While the predicate device requires power from a control box that is directly connected to a 110V outlet, the submission device requires only a small amount of power via USB from a laptop computer. The electrical safety of the PatCom Distal Chip Endoscope is further supported by the successful completion of the required electrical testing. For software, both contain image processing firmware and require a driver to connect imaging to a monitor. The difference lies in where the image processing chip is located, and what type of driver is required for the display monitor, of which the PatCom Distal Chip Endoscope is simpler (with the chip directly embedded within the endoscope) and easier to use (with the ability to plug and play and use any standard UVC driver. The other minor differences noted reflect enhanced features, such as having a wider field of view angle for better visualization, a smaller insertion tube outside diameter for safer intubation and patient comfort, and longer working length to allow for improved maneuverability. Therefore, these minor differences are not considered to raise different questions of safety and effectiveness compared to the predicate device.	

<table>
<tr><td colspan="2">Performance Characteristics</td><td colspan="2">The two devices have been submitted to an external accredited laboratory for extensive comparative imaging testing, such as Field of View (FOV, Depth of Field (DOF), Optimum Working Distance, Noise and Dynamic Range, Geometric Distortion, Image Intensity Uniformity (IIU), Color Performance and Latency Assessment for testing the Quality of the real-time video feed.

The tests conducted were performed in compliance with the following regulations:
– ISO 8600-1 (2005-05-1): Optics and photonics-Medical endoscopes and endotherapy devices-Part 1: General Requirements

– ISO 8600-3 (2019-8): Determination of field of view and direction of view of endoscopes with optics

– ISO 8600-5 (2020-10): Determination of optical resolution of rigid endoscopes with optics

– ISO 15739 (2017-05): Photography-Electronic still-picture imaging-Noise measurements

– ISO 12233 (2023-02): Photography-Electronic still picture imaging-Resolution and spatial frequency responses

All tests results have been determined to support both devices to be substantially equivalent.</td></tr>
<tr><td colspan="4">Material Characteristics</td></tr>
<tr><td colspan="4">Material:</td></tr>
<tr><td colspan="2">Bending section</td><td>Stainless steel</td><td>Stainless steel</td></tr>
<tr><td rowspan="2">Outer cover</td><td>Insertion Tube</td><td>Undefined “plastic materials”</td><td>TPU</td></tr>
<tr><td>Operation handle</td><td>Undefined “plastic materials”</td><td>ABS</td></tr>
<tr><td colspan="2">Disposable or not</td><td>Reuseable (high-level disinfection reprocessing)</td><td>Reuseable (high-level disinfection reprocessing)</td></tr>
<tr><td colspan="2">Discussion</td><td colspan="2">From the material characteristics compared above, we can see that most of the characteristics are the same, except the exact type of plastics used for the predicate device are undefined. The plastic material for the operation handle would only make skin contact with the user, but the plastic material covering the insertion tube would make direct mucosal membrane contact within the patient during the visualization. Concerning the Biocompatibility of the outer cover material of insertion tube which contacts the patients, we conducted a biocompatibility test, including Skin sensitization, Intracutaneous reactivity and in Vitro Cytotoxicity per ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2021. From result of the test, we can arrive at a conclusion that outer cover material of insertion tube is safe and biocompatible and does not raise different issues of safety or effectiveness.</td></tr>
</table>

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Below is a summary of the tests performed:

Non-Clinical Bench Performance Testing

Evaluation Description	Summary
Biological Evaluation	Evaluation of the biocompatibility of the materials contained within the device
Usability Evaluation	Evaluation of the usability of the device, it's IFU, and labels.
Lifetime Validation	Validation of the lifetime claims for the device.
Reprocessing Evaluation	Evaluation of the reprocessing for the device, and validation of the cleaning and high-level disinfection processes.
Electrical Safety Evaluation	Evaluation of the electrical safety testing of the device.
Software Evaluation	Evaluation of the software and its validation.
Design Verification and Validation	Evaluation of the design of the device.
Imaging Evaluation	Evaluation of the imaging of the device, and its comparison to the predicate device.

List of Applicable Standards

Reference	Description
MDR Regulation (EU) 2017/745	European Medical Device Regulations
EN ISO 13485:2016	Medical devices – Quality management systems – System requirements for regulatory purposes.
EN ISO 14971:2019 including deviations from EN ISO 14971:2012	Medical devices -- Application of risk management to medical devices
EN ISO 15223-1:2021	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1:General requirements
EN ISO 20417:2021	Information supplied by the manufacturer of medical devices

EN/IEC 60601-1-2:2014-(Ed.4.0)	Electromagnetic disturbances requirements and tests (EMC)
EN 60601-1:2015/A1:2013	Medical electrical equipment — General requirements for basic safety and essential performance
FCC Part 15 Subpart B:2015	Title 47 of the Code of Federal Regulations that covers EMC and is regulated by the Federal Communications Commission (FCC).
ICES-003:2020 Issue 7	Information Technology Equipment
CAN/CSA C22.2 No.60601-1:2014 (R2022)	The Canadian Electrical Code, Part II,
ANSI/AAMI/IEC 60601-1-2:2014/A1:2021	an American national standard that is equivalent to IEC 60601-1
IEC 60601-1-6 Ed. 3.1 b:2013	General requirements for basic safety and essential performance: Usability
IEC 62304:2006/Amd 1:2015	Medical device software – software life cycle processes
EN ISO 10993-1:2018	Biological evaluation of medical devices Part 1: Evaluation and testing
EN ISO 10993-5:2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2021	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
EN ISO 20695:2020	Catheters other than intravascular catheters -Test methods for common properties
EN IEC 62366-1:2015	Part 1: Application of usability engineering to medical devices
MEDDEV 2.12-1 rev 8, December 2013	Guidelines on a Medical Device Vigilance System.
MEDDEV 2.7/1: rev. 4, June 2016	Clinical evaluation: A guide for manufacturers and notified bodies.
MEDDEV 2.12/2 rev. 2 January 2012	Post market clinical follow-up studies; A guide for manufacturers and notified bodies
MDCG 2020-13	CER Report Template
MDCG 2020-5	Clinical Evaluation - Equivalence A guide for manufacturers and notified bodies
MDCG 2020-6	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies
MDCG 2020-8	Post-market clinical follow-up (PMCF) Evaluation Report Template A guide for manufacturers and notified bodies
MDCG 2019-9	Summary of safety and clinical performance A guide for manufacturers and notified bodies
ISO/IEC 17050-1:2007	Conformity assessment — Supplier's declaration of conformity — Part 1: General requirements
ANSI/AAMI ES60601-1:2005/A2:2021	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

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Non-Clinical Non-Performance Evaluations

Evaluation Description	Summary
Literature Review	Supports the safety and effectiveness of the device through the review of existing literature.
Risk Analysis	Assesses and reviews all the possible risks of the device, and any mitigation taken.

Conclusion:

All the non-clinical tests and evaluations that have been implemented either by the Original Manufacturer (WeSeeMed) or by Mui Scientific met the pre-defined criteria and showed that this device is as safe and effective as the predicate within its intended use.