February 21, 2020

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

Re: K192691
Trade/Device Name: PatCom Single-Use Introducer
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: December 13, 2019
Received: December 18, 2019

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,

for
Shani P. Haugen, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192691

Device Name
PatCom Single-Use Introducer

Indications for Use *(Describe)*

The Single-Use Introducer is used for patient esophageal intubation to guide the catheters and tubes via the nasal or oral cavity. It is to be used in conjunction with endoscopes to allow visualization of the placement process. The Single-Use Introducer is to be used in a hospital or clinical setting and under the supervision of a qualified healthcare professional who has received professional training in using the equipment.
The Single-Use Introducer is provided non-sterile, and is intended to be non-reusable.
The Single-Use Introducer is for transient use (under 24 hrs), and will come in direct contact with the patient's mucosal lining.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Mui Scientific
Division of H&A Mui Enterprises Inc.
145 Traders Blvd. E., Unit #34, Mississauga, ON, Canada, L4Z 3L3
Tel: (905) 890-5525 Toll Free: 1-800-303-6611 Fax: (905) 890-3523
Website: www.muiscientific.com Email: mail@muiscientific.com

February 10, 2020

510(k) Summary

RE: PatCom Single-Use Introducer

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**
Fax: **(905) 890-3523**
Email: **tammy.mui@muiscientific.com**

Trade name: **PatCom Single-Use Introducer**
Common name: **Introducer**
Classification name: **Endoscopes and accessories (as per CFR 876.1500)**

This 510(k) Summary is for the PatCom Single-Use Introducer

Indications for Use:

The Single-Use Introducer is used for patient esophageal intubation to guide the catheters and tubes via the nasal or oral cavity. It is to be used in conjunction with endoscopes to allow visualization of the placement process.

The Single-Use Introducer is to be used in a hospital or clinical setting and under the supervision of a qualified healthcare professional who has received professional training in using the equipment.

The Single-Use Introducer is provided non-sterile, and is intended to be non-reusable.

The Single-Use Introducer is for transient use (under 24 hrs), and will come in direct contact with the patient's mucosal lining.

Device Description:

The PatCom Single-Use Introducers are made from single lumen, medical grade polyvinyl chloride plastics. The tubing length is 30cm, with an open tip at one end, and a polycarbonate cone made of 2 halves at the other end.

This device is designed to work in conjunction with endoscopes to make the placement of certain catheters and tubes more pleasant for the patient and easier for the end user. The endoscope is placed inside the introducer and both devices together are guided through the

Mui Scientific
Division of H&A Mui Enterprises Inc.
145 Traders Blvd. E., Unit #34, Mississauga, ON, Canada, L4Z 3L3
Tel: (905) 890-5525 Toll Free: 1-800-303-6611 Fax: (905) 890-3523
Website: www.muiscientific.com Email: mail@muiscientific.com

nasal or oral passage into the pharynx, via the visual aid provided by the endoscope. The purpose of the visual aid is to prevent unnecessary aggravation of the nasopharyngeal or oropharyngeal wall. Once the introducer is in its desired position, the endoscope is extracted.

The introducer then functions as an open channel from the mouth or the tip of the nose through to the distal opening end of the introducer, as a guide for the placement of catheters and tubes, especially ones that do not contain their own open lumen for use of guidewires that are standard in the gastrointestinal industry. By feeding the catheters or tubes through the introducer, it again minimizes any possible aggravation of the pharyngeal wall as the catheters and tubes would follow the tunnel created by the introducer.

After the catheter is inserted through the introducer and placed into its proper positioning, the introducer is then extracted out of the nasal or oral cavity along the length of the catheter. Once the entire introducer is exposed, the user grips the 2 halves of the cone and pulls apart the introducer to remove and discard.

We are claiming equivalence to the following predicate device:

Product Name	510(k) Number	Manufacturer
Enteroscopy Overtube	**K100081**	**United States Endoscopy Group**

The PatCom Single-Use Introducers are similar to the overtubes manufactured by United States Endoscopy Group in that they have the same intended purpose, where both devices require the use of a scope, are slid over top of the endoscopic device, and are used to aid in the guidance of medical devices to be inserted into the upper gastrointestinal tract.

We would also like to acknowledge a reference device, listed below:

Product Name	510(k) Number	Manufacturer
Motility Catheters	**K823701**	**H&A Mui Enterprises Inc., o/a Mui Scientific**

The PatCom Single-Use Introducers are similar to the motility catheters manufactured by Mui Scientific in that they are also made of the same polyvinyl chloride (PVC) and polycarbonate (PC) material as the motility catheters, and are assembled following similar manufacturing procedures. They are both also intubated into a patient via the same nasal or oral cavity pathway.

Below, please find a comparison table of the PatCom Single-Use Introducer with the predicate device and reference device:

	Submission Device	Predicate Device	Reference Device
Trade name	PatCom Single-Use Introducer	Enteroscopy Overtube	Motility Catheters
510K holder	Submitter: H&A Mui Enterprises, o/a Mui Scientific	United States Endoscopy Group	H&A Mui Enterprises, o/a Mui Scientific
510K number	K192691	K100081	K823701
Indication for	The Single-Use Introducer is used for	The Enteroscopy	To be inserted via the

Mui Scientific Division of H&A Mui Enterprises Inc.
145 Traders Blvd. E., Unit #34, Mississauga, ON, Canada, L4Z 3L3
Tel: (905) 890-5525 Toll Free: 1-800-303-6611 Fax: (905) 890-3523
Website: www.muiscientific.com Email: mail@muiscientific.com

use	patient esophageal intubation to guide the catheters and tubes via the nasal or oral cavity. It is to be used in conjunction with endoscopes to allow visualization of the placement process. The Single-Use Introducer is to be used in a hospital or clinical setting and under the supervision of a qualified healthcare professional who has received professional training in using the equipment. The Single-Use Introducer is provided non-sterile, and is intended to be non-reusable.The Single-Use Introducer is for transient use (under 24 hrs), and will come in direct contact with the patient's mucosal lining.	Overtube is indicated for use to aid the insertion, advancement and removal of appropriately sized endoscopes and endoscopic devices during diagnostic and therapeutic endoscopic procedures in the upper gastrointestinal tract, including the small intestine.	nasal passage, orally, or anorectally, to measure the muscle contractions along the gastrointestinal system.
Device OD	5mm-6mm	Not found in the predicate 510(k) Summary	Various (2.5mm-6.2mm)
Device ID	4mm-5mm	Not found in the predicate 510(k) Summary	Various (0.4mm-3.3mm)
Material	PVC, PC	Not found in the predicate 510(k) Summary	PVC, PC, stainless steel
Length	30cm	Not found in the predicate 510(k) Summary	Various (100cm standard)
Number of uses	Single-use	Single-use	Single-use or reusable
Sterility status	Non-sterile	Non-sterile	Non-sterile

Nonclinical bench testing was carried out on the PatCom Single-Use Introducer to verify and validate its performance and intended use. Individual verification testing was conducted to verify the performance requirements and specifications of the introducer, such as dimensional verification, visual inspection, kink resistance testing, and tensile strength testing. Validation testing was then conducted on the user's needs and intended use. All testing and results were successfully completed, thereby demonstrating that the device is as safe, as effective, and performs as well as or better than the legally marketed device predicate.