September 29, 2021

Nissha Medical Technologies SAS
Roch Mignot
Quality & Regulatory Affairs Manager
ZA Des Boutries 12 Rue Des Cayennes
Conflans STE Honorine, Yvelines 78700
FRANCE

Re: K203350
Trade/Device Name: ENDOtube
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: OCX
Dated: August 12, 2021
Received: August 19, 2021

Dear Roch Mignot:

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
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203350

Device Name
ENDOtube

Indications for Use *(Describe)*
The ENDOtube devices are a combination of tubes, fittings and valves intended to provide sterile water and/or CO2 and/or air to an endoscope during gastrointestinal endoscopic procedure. These devices are intended to be used by healthcare professional only. In procedure room, all ENDOtube devices are 24 hours use disposable products except the one-way valves which are single use products and the insufflation connectors which are multiple patient use.

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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I. SUBMITTER

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Date Prepared: October 30, 2020 Date
Revised: December 30, 2020 Date
Latest Reviewed: August 03, 2021

II. DEVICE

Device / Property Name	ENDOtube
Common / Usual Name	Endoscopic tubing kit
Classification / Regulation Number 21CFR	876.1500
Classification Name	Endoscope and accessories
Product Code	OCX
Product Code Name	Endoscopic Irrigation/Suction System
Regulatory Class	II
Device Panel	Gastroenterology/Urology

The **ENDOtube** products include several families as detailed bellow in **VOL_002_Submission Context** in the file **005_Product List** and bellow.

Family	Reference	Description
ENDOtube for Wash Bottle	S-FLO000001	Sterile disposable tubing - Olympus GI endoscopes
	S-FLP000002	Sterile disposable tubing - Pentax GI endoscopes
	S-FLF000003	Sterile disposable tubing - Fujifilm GI endoscopes 5-600 series
	S-FLF000004	Sterile disposable tubing - Fujifilm GI endoscopes 700 series
	S-FLO001CO2	Sterile disposable tubing + CO2 option - Olympus GI endoscopes
	S-FLP002CO2	Sterile disposable tubing + CO2 option - Pentax GI endoscopes
	S-FLF003CO2	Sterile disposable tubing + CO2 option - Fujifilm GI endoscopes 5-600 series
	S-FLF004CO2	Sterile disposable tubing + CO2 option - Fujifilm GI endoscopes 700 series
ENDOtube for Insufflation	S-TUBCO2LUER	CO2 insufflation sterile tubing with hydrophobic filter - Luer connection
	S-TUBCO2FUJI	CO2 insufflation sterile tubing with hydrophobic filter - Adapter connection
	04628	Connection adapter for insufflator FUJIFILM GW-1
	04700	Connection adapter for insufflator OLYMPUS UCR
	04712	Connection adapter for insufflator FUJIFILM GW-100
ENDOtube for Wash Pump	S-PLO000100	Sterile disposable irrigation tubing - Emed pump/Olympus GI endoscopes
	S-PLO000300	Sterile disposable irrigation tubing - Olympus pump/Olympus GI endoscopes
	S-PLO000400	Sterile disposable irrigation tubing - Endogator pump/Olympus GI endoscopes
	S-PLO000600	Sterile disposable irrigation tubing - Erbe pump/Olympus GI endoscopes
	S-PLPPLF200	Sterile disposable irrigation tubing - Emed pump/Pentax-Fujifilm GI endoscopes
	S-PLPPLF500	Sterile disposable irrigation tubing - Endogator pump/Pentax-Fujifilm GI endoscopes
	S-PLPPLF700	Sterile disposable irrigation tubing - Erbe pump/Pentax-Fujifilm GI endoscopes
	S-100100	Sterile single use one-way water jet connector for Olympus
	S-100300	Sterile single use one-way water jet connector for Fujifilm
ENDOtube for Wash Bottle CO2 Insufflation	S-FLOCO2LUER	Sterile ENDOtube for Wash Bottle with CO2 tubing - for Olympus/Luer Insufflator Connection
	S-FLOCO2FUJI	Sterile ENDOtube for Wash Bottle with CO2 tubing - for Olympus/Adapter Insufflator Connection
	S-FLPCO2LUER	Sterile ENDOtube for Wash Bottle with CO2 tubing - for Pentax/Luer Insufflator Connection
	S-FLPCO2FUJI	Sterile ENDOtube for Wash Bottle with CO2 tubing - for Pentax/Adapter Insufflator Connection
	S-FLFCO2LUER	Sterile ENDOtube for Wash Bottle with CO2 tubing - for Fujifilm 5-600/Luer Insufflator Connection
	S-FLFCO2FUJI	Sterile ENDOtube for Wash Bottle with CO2 tubing - for Fujifilm 5-600/Adapter Insufflator Connection
	S-FLF7CO2LUER	Sterile ENDOtube for Wash Bottle with CO2 tubing - for Fujifilm 700/Luer Insufflator Connection
	S-FLF7CO2FUJI	Sterile ENDOtube for Wash Bottle with CO2 tubing - for Fujifilm 700/Adapter Insufflator Connection

III. PREDICATE DEVICE

In order to properly cover the entire product range of the application, two predicates have been selected. The primary predicate is **ENDOGATOR™** (K092429).

Device Name	**ENDOGATOR™**	**ENDO SMART CAP™**
510(k) Number	K092429	K093665
Class	II	II
Indications For Use	The ENDOGATOR™ system (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump (or cautery unit).	The ENDO SMARTCAP™ is intended to be used with an air or CO2 source and/or a pump along with a sterile water source to supply air or CO2 and sterile water to an endoscope during endoscopic procedures.

IV. Device Description

IV.1. General

The **ENDOtube** kits are a combination of tubes, fittings and valves intended to provide sterile water and/or CO2 and/or air to an endoscope during a GI endoscopic procedure.

Visual description of **ENDOtube** products in the endoscopic column can be found in the Figure 1.

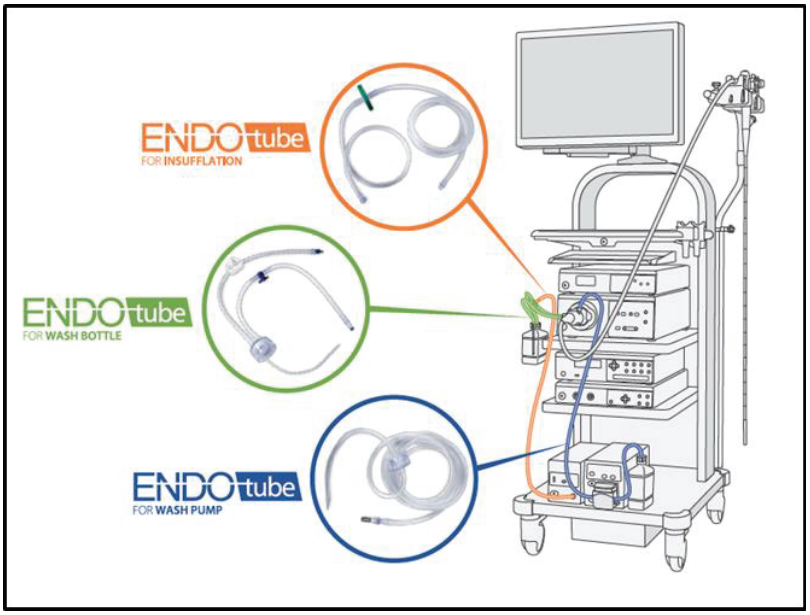

Figure 1: Visual description of the ENDOtube

The **ENDOtube** products are compatible with various endoscopes (FujiFilm® 500/600 series and 700 series, OLYMPUS® 140, 160, 180 and 190 and PENTAX®), and irrigation pumps (OLYMPUS®, Erbe® and EMED®).

IV.2. ENDOtube for Wash Bottle

The **ENDOtube for Wash Bottle** kits are a combination of tubes, fittings and valves intended to provide sterile water, air or CO2 to an endoscope during a GI endoscopic procedure.

The product is composed of at least two tubes bounded to a hermetic universal cap. The cap is screwed on a sterile water bottle. One tube is connected to the air output of the endoscopic column, and drive air into the bottle to put the sterile water bottle under pressure. The water is therefore forced into a second tube that is connected to the air/water channel of the endoscope. The device can also provide directly air or CO2 to the endoscope through another channel.

IV.3. ENDOtube for Wash Pump

The **ENDOtube for Wash Pump** kits are a combination of tubes, fittings and valves intended to provide sterile water to an endoscope through a peristaltic pump during a GI endoscopic procedure.

The product is composed of one or more tubes bounded one after another. On one extremity, the tube is inserted into sterile water bottle. On the other extremity the tube is connected to the water-jet channel of the endoscope. The central part is inserted into the pumping part of a peristaltic pump.

The **ENDOtube for Wash Pump** family contains also two independent single use one-way valves, used as an interface to connect the **ENDOtube for Wash Pump** tube to the endoscope waterjet channel.

IV.4. ENDOtube for Insufflation

The **ENDOtube for Insufflation** kits are a combination of tubes, fittings and filters intended to provide CO2 or air to an endoscope during a GI endoscopic procedure.

Form on side, the tube is connected to an independent CO2 or air supply. On the other side, it's connected to an **ENDOtube for Wash Bottle**. The product drive air or CO2 to put the sterile water bottle under pressure, to power it through the **ENDOtube for Wash Bottle** to the endoscope.

The **ENDOtube for Insufflation** family contains also three independent insufflation connectors used to adapt the **ENDOtube for Insufflation** tube to common independent CO2 or air supply devices.

IV.5. ENDOtube for Wash Bottle CO2 Insufflation

The ENDOtube for Wash Bottle CO2 Insufflation kits are a combination of tubes, fittings, valves and filters intended to provide sterile water and/or CO2 and/or air to an endoscope during a GI endoscopic procedure.

It's the combination of an ENDOtube for Wash Pump and an ENDOtube for Insufflation, bounded through a valve.

V. Indications for Use

The **ENDOtube** devices are a combination of tubes, fittings and valves intended to provide sterile water and/or CO2 and/or air to an endoscope during gastrointestinal endoscopic procedure. These devices are intended to be used by healthcare professional only. In procedure room, all **ENDOtube** devices are 24 hours use disposable products except the one-way valves which are single use products and the insufflation connectors which are multiple patient use.

VI. Technological characteristics comparison

Trade Name	ENDOtube (subject device)	ENDOGATOR™ (primary predicate)	ENDO SMARTCAP™
510(k) number	**K203350**	**K092429**	**K093665**
Intended Use	Endoscopic Accessories	Endoscopic Accessories	Endoscopic Accessories
Endoscope column compatibility	OLYMPUS® GI endoscopes 140, 160, 180 and 190	OLYMPUS® GI endoscopes 140, 160, 180 and 190	OLYMPUS® GI endoscopes 140, 160 and 180
	PENTAX® GI endoscopes	PENTAX® GI endoscopes	PENTAX® GI endoscopes
	FUJIFILM® GI 500/600 series and 700 series endoscopes	N/A	FUJIFILM® GI 500/600 series and 700 series endoscopes
Irrigation peristatic pump compatibility	OLYMPUS®, Erbe®, EMED®	OLYMPUS®, Erbe®, EMED®	OLYMPUS®, Erbe®, EMED®
Insufflator compatibility	OLYMPUS® UCR, FUJIFILM® GW-1 and GW-100	Not compatible with OLYMPUS® or FUJIFILM® GW-1 and GW-100	N/A
Universal water bottle cap	Common sterile water bottle brands	Common sterile water bottle brands	Common sterile water bottle brands
Fluid supply	Sterile water; Air; CO_2	Sterile water	Sterile water; Air; CO_2
One-way valve (for irrigation pump compatible device)	Present	Present	Present
Tube use period	Multi-patient use, without reprocessing Up to 24 hours	Multi-patient use, without reprocessing Up to 24 hours	Multi-patient use, without reprocessing Up to 24 hours
One-way valve use period	Single use Up to 2 hours	Single use Not communicated but expected to be up to 2 hours	Single use Not communicated but expected to be up to 2 hours
Insufflation connector use period	Multi-patient use	N/A	N/A
Insufflation connector process	Reprocessable	N/A	N/A
Device shelf-life	2 years	2 years	2 years
Tube and valve sterilization	EO sterilization	EO sterilization	EO sterilization
Insufflation connector sterilization	Non-sterile	N/A	N/A
Main materials	Biocompatible	Biocompatible	Biocompatible
	Inert metallic materials, elastomers and thermoplastic polymer	Inert metallic materials, elastomers and thermoplastic polymer	Inert metallic materials, elastomers and thermoplastic polymer
	Not made with DEHP	Contain DEHP	Contain DEHP
Device tissue contact	Intestinal mucosa indirect contact for the patient Skin direct contact for the end-user	Intestinal mucosa indirect contact for the patient Skin direct contact for the end-user	Intestinal mucosa indirect contact for the patient Skin direct contact for the end-user
Tube materials	PVC/Silicone	PVC/Silicone	PVC/Silicone
Connector and valve materials	SAN/ABS	SAN/ABS	SAN/ABS

Trade Name	ENDOtube (subject device)	ENDOGATOR™ (primary predicate)	ENDO SMARTCAP™
510(k) number	**K203350**	**K092429**	**K093665**
Bottle cap material	PC	PE/SAN	PE/SAN
Bottle cap seal material	TPU	Silicone	Silicone
Testing	Fluid and Pressure Testing, flow rated data	Not provided in 510(k) summary	Not provided in 510(k) summary

VII. Substantial Equivalence Discussion

Based on the above comparison of intended use, endoscope compatibilities, testing methods and construction materials employed, the subject device **ENDOtube** (multiple models) are substantially equivalent to the two named predicates. The main asset of a device that is intended to provide sterile water, air or CO2 to an endoscope are the safety of use and the compatibility of the product with the environment of a medical theater.

The comparison between **ENDOtube** devices and the predicates are mainly based on these attributes.

- Compatibility with the main endoscope, pump and sterile water bottle available on the market
- Ability to provide sterile water, air or CO2
- Sterilized, cross-contamination proof devices
- Main materials used

VIII. Non-clinical Testing Summary

Description	Parameter	Test description	Conclusion
Endoscope column compatibility	OLYMPUS® GI endoscopes 140, 160, 180 and 190	Connection and usability testing	Pass
	PENTAX® GI endoscopes	Connection and usability testing	Pass
	FUJIFILM® GI 500/600 series and 700 series endoscopes	Connection and usability testing	Pass
Irrigation peristaltic pump compatibility	Olympus®, Erbe®, EMED®	Connection and usability testing	Pass
Insufflator compatibility	OLYMPUS® UCR, FUJIFILM® GW-1 and GW-100	Connection and usability testing	Pass
Universal water bottle cap	Presence and effectiveness	Connection and usability testing	Pass
Fluid supply	Sterile water; Air; CO_2	Leak test and usability testing	Pass
One-way valve (for irrigation pump compatible device)	Presence and effectiveness	Cross-contamination test	Pass
Tube use period	Multi-patient use, without reprocessing Up to 24 hours	Durability test	Pass
One-way valve use	Single use	Operational test	Pass

Description	Parameter	Test description	Conclusion
period	Up to 2 hours		
Device shelf-life	2 years	Performance test	Pass
Insufflation connector use period	Multi-patient use	Operational test	Pass
Insufflation connector processing	Reprocessable	Performance test	Pass
Tube and valve sterilization	EO sterilization	Sterilization validation	Pass
Main materials	Biocompatible	Biocompatibility testing (AAMI/ISO 10993)	Pass
	Inert metallic materials, elastomers and thermoplastic polymer	Biocompatibility testing (AAMI/ISO 10993)	Pass
	No DEHP	Chemical characterization	Pass

IX. Clinical Testing

Not required for a finding of substantial equivalence.

X. Conclusion

Based on the above comparisons of intended use, endoscope, testing methods and construction materials employed, the subject device **ENDOtube** (multiple models) are substantially equivalent to the two named predicates. The main asset of a device that is intended to provide sterile water, air or CO2 to an endoscope are the safety of use and the compatibility of the product with the environment of a medical theater. The comparison between **ENDOtube** devices and the predicates are mainly based on these following attributes:

- Compatibility with the main endoscope, pump and sterile water bottle available on the market;
- Ability to provide sterile water, air or CO_2;
- Sterilized, cross-contamination proof devices;
- Main materials used.

Therefore, the ENDOtube is substantially equivalent to the named predicate devices.