January 6, 2021

Wilson Instruments (SHA) Co., LTD
Juan Wu, MS
Building 5, No. 258 Shuangbang Rd.
Xujing Town Qingpu Dist
Shanghai, 201702
CHINA

Re: K200769
Trade/Device Name: Disposable Endoscope Valves Set,
Disposable Endoscope Valves Set B
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODC
Dated: November 20, 2020
Received: November 27, 2020

Dear Juan Wu:

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)*
K200769

Device Name
Disposable Endoscope Valves Set
Disposable Endoscope Valves Set B

Indications for Use *(Describe)*
The Disposable Endoscope Valves Set is a collection of several sterile units. It is intended to be fitted to multiple endoscope working channels/ports to control the flow of fluids, gases and other materials. It includes an air/water valve, a suction valve, a biopsy valve and a water connector.

- Disposable Air/Water Valves: This unit is intended to be fitted to an endoscope air/water channel to control the inflow of medical gases and water, whilst preventing back-flow.
- Disposable Suction Valves: This unit is intended to be fitted to an endoscope suction channel to control the operations of suction, whilst preventing inflow of air.
- Disposable Biopsy Valves: This unit is intended to be fitted to an endoscope biopsy port to prevent leakage of gases and body fluids during an endoscopic procedure.
- Disposable Endoscope Water Connectors: This unit is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.

The Disposable Endoscope Valves Set B is a collection of sterile device intended to be fitted to multiple endoscope working channels/ports to enable an endoscope operator control the function of the working channels/ports and prevent retrograde flow of fluids, gases, and other materials. It includes a suction valve, an air/water valve. This is a single-use device.

- Air/Water Valves: This device is intended to be fitted to an endoscope air/water channel to enable the operator to control inflow of medical gases and water, whilst preventing backflow.
- Suction Valves: The device is intended to be fitted to an endoscope suction channel to enable the operator to control suction whilst preventing inflow of air.

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

I. Submitter

Device submitter: WILSON INSTRUMENTS (SHA) CO., LTD
Building 5, No.258 Shuangbang Rd., Xujing Town Qingpu Dist,
Shanghai, CHINA, 201702

Primary contact person: Juan Wu
Regulatory Affairs
Phone: +86 21-39290696 ext 8027
Email: wilson.ra803@wilson.sh.cn

Date of preparation: Nov.20, 2020.

II. Device

Trade Name of Device: Disposable Endoscope Valves Set, Disposable Endoscope Valves Set B
Common name: Endoscope and accessories
Regulation Number: 21 CFR 876.1500
Regulatory Class: II
Product code: ODC
Review Panel: Gastroenterology/Urology

III. Predicate Devices

Trade name: DEFENDO™ Disposable Air/Water Valve for GI Endoscopes
Common name: Endoscopes and accessories
Classification: Class II, 21 CFR 876.1500
Product Code: ODC
Premarket Notification: K102409
Manufacturer: Medivators Inc formerly Byrne Medical

Trade name: DEFENDO™ Disposable Suction Valve for GI Endoscopes
Common name: Endoscopes and accessories
Classification: Class II, 21 CFR 876.1500
Product Code: ODC, FDF
Premarket Notification: K102581
Manufacturer: Medivators Inc formerly Byrne Medical

Trade name: DEFENDO™ Biopsy Valve for Olympus and Fujinon Endoscopes
DEFENDO™ Biopsy Valve for Pentax Endoscopes

Common name: Endoscopes and accessories
Classification: Class II, 21 CFR 876.1500
Product Code: ODC
Premarket Notification: k090851
Manufacturer: Medivators Inc formerly Byrne Medical

Trade name: EndoGator™ System
Common name: Endoscopes and accessories
Classification: Class II, 21 CFR 876.1500
Product Code: FEQ
Premarket Notification: k092429
Manufacturer: Medivators Inc formerly Byrne Medical

IV. Device description

The Disposable Endoscope Valves Set is a collection of several sterile units. It is intended to be fitted to multiple endoscope working channels/ports to control the flow of fluids, gases and other materials. It includes an air/water valve, a suction valve, a biopsy valve and a water connector.

The Disposable Endoscope Valves Set B is a collection of sterile device intended to be fitted to multiple endoscope working channels/ports of Pentax GI Video Endoscopes to enable an endoscope operator control the function of the working channels/ports and prevent retrograde flow of fluids, gases, and other materials. It includes a suction valve, an air/water valve.

V. Indications for use

The Disposable Endoscope Valves Set is a collection of several sterile units. It is intended to be fitted to multiple endoscope working channels/ports to control the flow of fluids, gases and other materials. It includes an air/water valve, a suction valve, a biopsy valve and a water connector.

- Disposable Air/Water Valves: This unit is intended to be fitted to an endoscope air/water channel to control the inflow of medical gases and water, whilst preventing back-flow.
- Disposable Suction Valves: This unit is intended to be fitted to an endoscope suction channel to control the operations of suction, whilst preventing inflow of air.
- Disposable Biopsy Valves: This unit is intended to be fitted to an endoscope biopsy port to prevent leakage of gases and body fluids during an endoscopic procedure.
- Disposable Endoscope Water Connectors: This unit is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.

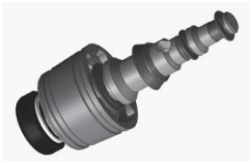
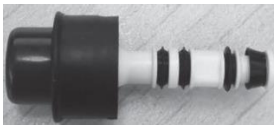
The Disposable Endoscope Valves Set B is a collection of sterile device intended to be fitted to multiple endoscope working channels/ports to enable an endoscope operator control the function of the working channels/ports and prevent retrograde flow of fluids, gases, and other materials. It includes a suction valve, an air/water valve.

- Air/Water Valves: This device is intended to be fitted to an endoscope air/water channel to enable the operator to control inflow of medical gases and water, whilst preventing backflow.
- Suction Valves: The device is intended to be fitted to an endoscope suction channel to enable the operator to control suction whilst preventing inflow of air.

VI Comparison of technological characteristics with the predicate devices

The Disposable Endoscope Valves Set and Disposable Endoscope Valves Set B have similar technological characteristics and fundamental design as the predicate device. The differences between the subject device and predicate devices do not alter suitability of the proposed device for its intended use.

Table 1 Substantial equivalence discussion – Disposable Air/Water Valve

Device feature	**Disposable Air/Water Valves (subject device)**	**DEFENDO™ Disposable Air/Water Valve k102409 (predicate device)**	**Discussion**
Picture	WS-VO-01  WS-VP-01 		Same structure
Indications for use	The device is intended to be fitted to an endoscope air/water channel to control the inflow of medical gases and water, whilst preventing back-flow.	The DEFENDO™ Disposable Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure.	Substantially equivalent. Both devices are used with the endoscopes to control the air/water function.
Product code	ODC	ODC	Substantially equivalent.
Regulation number	21 CFR 876.1500	21 CFR 876.1500	Identical
Classification	II	II	Identical

Compatible endoscopes	WS-VO-01: Olympus 140/160/180/190/240/260/290 series endoscopes WS-VP-01: PENTAX GI Video Endoscope 90K/90i Series; K10/i10 Series	Olympus 140/160/180/240/260 series endoscopes	Substantially equivalent supported by performance testing.
Sterile	EO sterilization	EO sterilization	Identical
Single Use	Yes	Yes	Identical
Material	WS-VO-01: SIR, ABS, TPE, Stainless steel 304 WS-VP-01: SIR, ABS, TPE, Stainless steel 304	PC, TPE, Stainless steel 304	Substantially equivalent, both devices are evaluated according to ISO 10993-1.
Environment of use	Hospitals/clinics	Hospitals/clinics	Identical

Table 2 Substantial equivalence discussion – Suction Valve

Device feature	**Disposable Suction Valves (subject device)**	**DEFENDO™ Disposable Suction Valve for GI Endoscopes k102581 (predicate device)**	**Discussion**
Picture	WS-VO-02  WS-VP-02 		Same structure
Indications for use	The device is intended to be fitted to an endoscope suction channel to control the operations of suction, whilst preventing inflow of air.	The DEFENDO™ Disposable Suction Valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.	Substantially equivalent. Both devices are used with the endoscopes to control the suction function.
Product code	ODC	ODC	Substantially equivalent.
Regulation number	21 CFR 876.1500	21 CFR 876.1500	Identical
Classification	II	II	Identical
Compatible endoscopes	WS-VO-02: Olympus 140/160/180/190/240/260/290 series endoscopes WS-VP-02: PENTAX GI Video Endoscope 90K/90i Series; K10/i10 Series	Olympus 140/160/180/190/240/260 series endoscopes	Substantially equivalent supported by performance testing.
Sterile	EO sterilization	EO sterilization	Identical
Single Use	Yes	Yes	Identical

Material	WS-VO-02: SIR, ABS, TPE, Stainless steel 304, Stainless steel 17-4PH WS-VP-02: SIR, ABS, TPE, Stainless steel 304	NBR, PC, TPE, Stainless steel 304	Substantially equivalent, both devices are evaluated according to ISO 10993-1.
Environment of use	Hospitals/clinics	Hospitals/clinics	Identical

Table 3 Substantial equivalence discussion – Biopsy Valve

Device feature	**Disposable Biopsy Valves (subject device)**	**DEFENDO™ Biopsy Valve k090851 (predicate device)**	**Discussion**
Picture			Same structure
Indications for use	The device is intended to be fitted to an endoscope biopsy port to prevent leakage of gases and body fluids during an endoscopic procedure	The DEFENDO™ Disposable Biopsy Valve is indicated for covering the endoscope biopsy port during an endoscopy procedure. The valve provides access for endoscopic device passage and exchange, helps maintain sufflation and minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure.	Substantially equivalent. Both devices are used on the endoscopes biopsy port to prevent leakage.
Product code	ODC	ODC	Substantially equivalent.
Regulation number	21 CFR 876.1500	21 CFR 876.1500	Identical
Classification	II	II	Identical
Compatible endoscopes	Olympus 140/160/180/190/240/260/290 series endoscopes	Olympus GI endoscopes	Substantially equivalent, both devices are used for Olympus GI endoscopes.
Sterile	EO sterilization	EO sterilization	Identical

Single Use	Yes	Yes	Identical
Material	Silicon rubber	TPE	Different while both devices are evaluated according to ISO 10993-1.
Environment of use	Hospitals/clinics	Hospitals/clinics	Identical

Table 4 Substantial equivalence discussion – Water Connector

Device feature	**Disposable Endoscope Water Connectors (subject device)**	**EndoGator™ System k092429 (predicate device)**	**Discussion**
Indications for use	The device is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.	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)	Substantially equivalent. Both devices are used to provide irrigation during GI endoscopic procedures.
Picture			The predicate water connector is a component of the EndoGator™ system. Both devices consist of luer taper to be connected to the water tubing, connector be connected to the endoscope and the intermediate check piece to prevent backflow.
Product code	ODC	FEQ	Different as the predicate device consists of a pump, tubing and accessories.
Regulation number	21 CFR 876.1500	21 CFR 876.1500	Identical

Classification	II	II	Identical
Compatible endoscopes	Olympus 140/160/180/190/240/260/290 series endoscopes	Olympus GI endoscopes	Substantially equivalent, both devices are used for Olympus GI endoscopes.
Sterile	EO sterilization	EO sterilization	Identical
Single Use	Yes	Yes	Identical
Material	SIR, PVC, PC, Stainless steel 303	NBR, SIR, ABS	Different while both devices are evaluated according to ISO 10993-1.
Environment of use	Hospitals/clinics	Hospitals/clinics	Identical

VII Performance data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Biocompatibility of the Disposable Endoscope Valves Set and Disposable Endoscope Valves Set B were evaluated in accordance with ISO 10993-1:2009 for the body contact category of "Surface – Mucosal Membrane" with a contact duration of "Limited (< 24 hours)". The following tests were performed, as recommended: Cytotoxicity, Irritation and Sensitization. All evaluation acceptance criteria were met.

Performance testing

WILSON INSTRUMENTS (SHA) CO., LTD has performed bench testing to support substantial equivalence. The following tests were performed on the subject devices and predicate devices.

Disposable Air/Water Valves WS-VO-01:

- Time of inflation of 8KPa air
- Time of injection of 10g water

Disposable Suction Valves WS-VO-02:

- Time of suction of 200g water

Disposable Biopsy Valves WS-M-01S:

- Plug-in performance: Depression force, pull out force
- Sealing performance: Leakage test, flush open force
- Fitting test

Disposable Endoscope Water connectors WS-VO-03:

- Leakage test under 80Kpa forward pressure
- Leakage test under 30Kpa reverse pressure

Disposable Air/Water Valves WS-VP-01:

- Amount of water feeding
- Amount of air feeding
- Depression force
- Sealing performance

Disposable Suction Valves WS-VP-02:

- Amount of suction
- Depression force

Sterilization and Shelf-life testing

The sterilization method has been validated to ISO11135, which has thereby determined the routine control and monitoring parameters. 3-year shelf-life of the device has been evaluated by accelerated aging test.

VIII Conclusion

The Disposable Endoscope Valves Set and Disposable Endoscope Valves Set B are substantially equivalent to the predicate devices. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.