



Food and Drug Administration
10903 New Hampshire Avenue
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December 10, 2015

Wilson Instruments (Shanghai) Company Limited
Lijuan Zhang
Regulatory Affairs Manager
Building 5, No.258 Shuangbang Road
Xujing Town, Qingpu District
Shanghai China

Re: K151714
Trade/Device Name: Disposable Endoscope Valves Set A
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODC
Dated: November 6, 2015
Received: November 10, 2015

Dear Lijuan Zhang,

This letter corrects our substantially equivalent letter of December 3, 2015.

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.

Director

Division of Reproductive, Gastro-Renal,
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

008_Indications for Use

Indications for Use

510(k) Number (if known): K151714

Device Name: Disposable Endoscope Valves Set A

Indications for Use: 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 typically includes a suction valve, an air/water valve, and a biopsy valve. This is a single-use device.

Prescription Use **X** AND/OR Over-The-Counter Use
 (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

 Concurrence of CDRH, Office of In Vitro Diagnostic Devices and Radiological Health
 (OIR)

 (Division Sign-Off)
 Division of Radiological Health
 Office of *In Vitro* Diagnostics and Radiological Health
 510(k) _____

510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR807.92 (a) (1)]

Jun 23th, 2015

2. Submitter's Information [21 CFR807.92 (a) (1)]

Name of Sponsor: Wilson Instruments (Shanghai) Company Limited
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Contact Name: Xin HUANG
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Email Address: xhuang@heyinovo.com

3. Trade Name, Common Name, Classification [21 CFR807.92(a)(2)]

Trade Name: Disposable Endoscope Valves Set A
Model Name: VO series, M series
Common Name: Endoscope Channel Accessory
Regulatory Classification: 21 CFR876.1500 Endoscope and Accessories
Product Code: ODC
Classification Panel: Gastroenterology/Urology
Device Class: II

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicates within this submission are as follows:

OLYMPUS CORP. OLYMPUS DISPOSABLE SUCTION VALVE has been cleared by FDA through 510(k) No.K920025 (Decision Date -03/24/1992).

OLYMPUS CORP. OLYMPUS DISPOSABLE BIOPSY VALVE has been cleared by FDA through 510(k) No.K911412 (Decision Date -06/28/1991).

THE OLYMPUS OPTICAL CO. EVIS EXERA COLONOVIDEOSCOPE CF-Q160 AL/I AND PCF-160 AL/I(MH-438) have been cleared by FDA through 510(k) No.K001241 (Decision Date -05/09/2000).

5. Description of the Device [21 CFR 807.92(a)(4)]

Wilson's Disposable Endoscope Valves Set A collects three types of valve products into one package unit. Disposable Endoscope Valves Set A can make it convenient for the replacement of Air/Water Valves, Suction Valves, Biopsy Valve during an endoscopic procedure. And these three types' valves can realize their intended uses respectively.

6. Intended Use [21 CFR 807.92(a)(5)]

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 typically includes a suction valve, an air/water valve, and a biopsy valve. This is a single-use device.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

As the reason that the working situation, environment and the intended use of Wilson's Disposable Endoscope Valves Set A are the same as the intended uses' combination from the similar Olympus Disposable Suction Valve, Olympus Disposable Biopsy Valve and EVIS EXERA COLONOVideoscope CF-Q160 AL/I AND PCF-160 AL/I(MH-438), the technological characteristics of this product series are designed to make same as that of the equivalence product, including product structure for compatible endoscope, and the application of materials over different parts of the product series are also designed to be equal or better respectively and etc. It applies EO sterilization method, which is also same as that of SE product.

8. Substantial Equivalence [21 CFR 807.92(b) (1) and 807.92]

The Disposable Endoscope Valves Set A of Wilson has taken the biocompatibility, sterility and performance testing into concern in accordance to Food and Drug Administration related guidance and recognized international standards. Test data and report information are included in this submission.

9. Conclusion [21 CFR 807.92(b) (3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Wilson Instruments (Shanghai) Company Limited concludes that Disposable Endoscope Valves Set A is substantially equivalent to predicate devices with regard to safety and effectiveness.