May 14, 2018

Zhejiang Chuangxiang Medical Technology Co., LTD.
Lucius Long
Quality Supervisor
301B, No.22, XinYan Road
Hanzhou, Zhejiang 311100
China

Re: K173758
Trade/Device Name: Disposable Biopsy Valve
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: OCX
Dated: April 18, 2018
Received: April 18, 2018

Dear Lucius Long:

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.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173758

Device Name
Disposable Biopsy Valve

Indications for Use *(Describe)*
The Disposable Biopsy Valve is used to cover the opening to the biopsy/suction channel of Olympus® and Fujinon® or Pentax® gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

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.

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Zhejiang Chuangxiang Medical Technology Co.,Ltd

Section 3 510(k) Summary(21CFR 807.92)

1. Submitter's information

Name: Zhejiang Chuangxiang Medical Technology Co., LTD.

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Contact person: Lucius.Long
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2. Device

Trade Name: Disposable Biopsy Valve
Common Name: Disposable Biopsy Valve
Regulation class: 2
Panel: Gastroenterology/Urology
Classification name: Endoscope and accessories
Regulation number:876.1500
Product code: OCX

3. Predicative device

3.1) 510(k) Number:K142068,
Product Name: Medovations BullDog® Biopsy Valves
3.2) 510(k) Number: K161167,
Product Name: Seal Single-use Biopsy Valve

4. Device description

The Disposable Biopsy Valve is provided non-sterile or sterile, and is composed of a cylindrical base and a connected cap. The Disposable Biopsy Valve provides sealable access via the working channel port of an endoscope for surgical instruments. The valve consists of an attached cap and valve body with a circular opening. The cap is pre-perforated, and ensures instrument access and removal is tight and leak-free. The valve is designed with a hollow body with a distal end that releasably attaches to the inlet port of the working channel. The valve body provides a flexible diaphragm seal that separates the body into a proximal chamber and distal chamber. The distal chamber secures onto the endoscope, while the proximal chamber secures the cap. Instruments are inserted through the cap and chambers, through the diaphragm seal, and into the endoscope. The diaphragm seal is configured such that a seal is formed due to deformation of the elastomer around an instrument when it is inserted

through the opening, preventing fluids from passing through the biopsy valve. The cap serves two primary functions. One function of the cap is to provide an additional seal around surgical instruments to prevent leakage. The second function is to allow modification of pressure during insufflation by opening the cap, allowing gasses to flow from the endoscope, and out of the biopsy valve.

5. Indication for use

The Disposable Biopsy Valve is used to cover the opening to the biopsy/suction channel of Olympus® and Fujinon® or Pentax® gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

6. Technological Characteristics

The Disposable Biopsy Valve incorporates substantially equivalent device materials, design, configuration, packaging fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate devices.

Comparison to predicate Devices:

Item	Proposed device	Primary Predicate device	Additional Predicate device	Comparison to Predicate Devices
Device name	Disposable Biopsy Valve	Medovations BullDog® Biopsy Valves	Seal Single-use Biopsy Valve	Similiar
510(k) number	NA, new submission	K142068	K161167	Different 510(k) number
Manufacturer	Zhejiang Chuangxiang medical technology Co., Ltd.	Medovations, Inc.	Endochoice, Inc.	Different manufacturer
Product Code	OCX	OCX	OCX	Same
Regulation No.	876.1500	876.1500	876.1500	Same
Class	2	2	2	Same
Regulation Name	Single piece injection molded	Single piece injection molded	Single piece injection molded	Same
Supplied Sterile	non-sterile or sterile	non-sterile or sterile	non-sterile or sterile	Same
Sterilization method	EO gas	EO gas	EO gas	Same
Material	Thermoplastic elastomer	Thermoplastic elastomer	Thermoplastic elastomer	Same
Valve Inner Diameter	.071"	.065"	7.1 mm	Similar

Removable Cap with Slit for Device Passage	Yes	Yes	Yes	Same
Slit accommodate devices	Up to 3.2 mm	/	Up to 3.2 mm	Same
Biocompatiblity	Tested in accordance with ISO 10993-1	No direct patient contact. Indirect patient contact from devices and/or irrigating solution that is in contact with the biopsy valve and accessory irrigating adaptor.	Tested in accordance with ISO 10993-1	Same
Endoscope compatibility	Molded versions to fit biopsy/suction channel of Olympus/Fujinon gastrointestinal endoscopes or biopsy/suction channel of Pentax gastrointestinal endoscopes	Molded versions to fit biopsy/suction channel of Olympus/Fujinon gastrointestinal endoscopes or biopsy/suction channel of Pentax gastrointestinal endoscopes	Olympus series 160, 180, and 190. Fujinon series 530, 590, and 600. EndoChoice Fuse gastrointestinal endoscopes	Same

Indications for Use	The Disposable Biopsy Valve is used to cover the opening to the biopsy/suction channel of Olympus® and Fujinon® or Pentax® gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.	The single use BullDog® Biopsy Valve is used to cover the opening to the biopsy/suction channel of Olympus® and Fujinon® or Pentax® gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.	The Single-Use Biopsy Valve provides access for endoscopic device passage and exchange, helps maintain sufflation, and minimizes leakage of biomaterial from biopsy port throughout the endoscopic procedure, and provides access for irrigation.	Same
Single Use	Yes	Yes	Yes	Same
Packaging	BILLERUD (2010)70g pouch with 52μm PE/PET	Tyvek pouch with a polyethylene film	Tyvek pouch with a polyethylene film	Similar
Performance testing	Design verification Pressure test with valve closed - the device holds pressure for 1 Min at 10 PSI	/	Design verification Pressure test with valve closed - the device holds pressure for 1 Min at 10 PSI	Same

	Design verification Pressure test with instrument inserted - the device holds pressure for 1 Min at 10 PSI	/	Design verification Pressure test with instrument inserted - the device holds pressure for 1 Min at 10 PSI	Same
	Design verification Pressure test: Following removal of instrument the device holds pressure for 1 Min at 10 PSI	/	Design verification Pressure test: Following removal of instrument the device holds pressure for 1 Min at 10 PSI	Same

The main difference is the dimension about Valve Inner Diameter , because their criteria are different. The inner diameter criterion of primary predicate device is 1.651mm (.065") and the proposed device is1.81mm(.071"). But they each meet their own design requirements, usually, the O.D. of the devices ≥2.0mm used cooperatively with the inner diameter of the biopsy valve. So we think the proposed device meet the Clinical requirements, the proposed device and predicate device are substantial equivalent.

7. Non-Clinical Testing:

The device has undergone both bench testing of performance and laboratory biocompatibility testing for cytotoxicity, sensitization, intracutaneous injection test, and system injection test, in accordance with 21 CFR, Part 58. The Single Use Biopsy Valve results in no safety or efficacy concerns regarding biocompatibility or performance. Likewise, in conformance with 21 CFR 807.92(b)(3), the device performs as well as the predicate in all testing performed.

8. Conclusions

Chuangxiang medical has demonstrated that the proposed Disposable Biopsy Valve is substantially equivalent to Medovations and Endochoice, Inc. currently marketed Medovations BullDog® Biopsy Valves (K142068) and Seal Single-use Biopsy Valve (K161167).