DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 26, 2016

Endochoice, Inc.
Daniel Hoefer
Manager, Regulatory Affairs
11810 Wills Road
Alpharetta, GA 30009

Re: K161167
Trade/Device Name: Seal Single-use Biopsy Valve
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCX
Dated: April 22, 2015
Received: April 26, 2016

Dear Daniel Hoefer,

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" (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.

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

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)*
K161167

Device Name
Seal Biopsy Valve

Indications for Use *(Describe)*
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.

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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510(k) Summary

Seal Single-Use Biopsy Valve

May 26, 2016

1. **Company Identification**

EndoChoice, Inc.
11810 Wills Road
Alpharetta, GA 30009
Telephone: 678-708-4743
Fax: 678-567-8218
Establishment Registration: 3007591333

2. **Contact Person**

Daniel Hoefer
Regulatory Affairs Manager

3. **Device Name**

Commercial Name:	Seal® Single-Use Biopsy Valve
Common/Usual Name:	Biopsy Valve
Classification Name:	Endoscopic, irrigation/suction system

4. **Device Classification**

Product Code:	OCX
Regulation Number:	876.1500
Class:	II
Review Panel:	Gastroenterology/Urology

5. **Intended Use:**

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.

6. **Device Description:**

The Seal® Single-Use Biopsy valve is provided non-sterile or sterile, and is composed of a cylindrical base and a connected cap. The Single-Use 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.

7. Substantial Equivalence:

The device submitted for review is a modification of the Biopsy Valve (K133734). Changes to the device include a modification in material. Both the modified and unmodified device is composed of thermoplastic elastomers. The modified device also has a reduction in overall height of the biopsy valve to provide an improved fit between the cap and body, as well as the valve to the instrument port.

The modified device is identical in terms of intended use, operating principle, performance, technology, energy used, and packaging.

Characteristic	Single-Use Biopsy Valve (Unmodified)	Single-Use Biopsy Valve (Modified)
510(k) number	K133734	Pending
Indications for Use	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.	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.
Material	Thermoplastic elastomer	Thermoplastic elastomer
Valve Inner Diameter	7.1 mm	7.1 mm
Biocompatiblity	Tested in accordance with ISO 10993-1	Tested in accordance with ISO 10993-1
Endoscope compatibility	Olympus series 160, 18180, and 190. Fujinon series 530, 590, and 600. EndoChoice Fuse gastrointestinal	Olympus series 160, 180, and 190. Fujinon series 530, 590, and 600. EndoChoice Fuse gastrointestinal

Characteristic	Single-Use Biopsy Valve (Unmodified)	Single-Use Biopsy Valve (Modified)
	endoscopes	endoscopes.
Removable cap with slit	Yes	Yes
Slit accommodate devices	Up to 3.2 mm	Up to 3.2 mm
Packaging	Individually packaged plastic pouch or sterile pouch	Individually packaged plastic pouch or sterile pouch
Performance testing:	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	Same
	Design verification Pressure test: Following removal of instrument the device holds pressure for 1 Min at 10 PSI	Same

8. Non-Clinical Testing:

The modified 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 modified 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 modified device performs as well as the predicate in all testing performed.

9. Conclusion:

The modified Single-Use Biopsy Valve is substantially equivalent to the unmodified predicate device listed above in performance, technical characteristics, biocompatibility, and intended use.