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 19, 2016

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

Re: K160403
Trade/Device Name: SmartStart™ Air/Water and Suction Valves
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: ODC
Dated: May 4, 2016
Received: May 5, 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)*

K160403

Device Name
SmartStart™ Air/Water and Suction Valves

Indications for Use *(Describe)*

The SmartStart™ air/water valve is intended be used to control the air/water function on an endoscope during a GI endoscopic procedure.

The SmartStart™ suction valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# Traditional 510(k) Summary

## 1. Company Identification

EndoChoice, Inc.
11810 Wills Road
Alpharetta, GA 30009
Telephone (678) 708 4743
FAX (678) 878 3373
Establishment Registration: 3007591333

## 2. Contact Person

Daniel Hoefer
Regulatory Affairs Manager

## 3. Device Name

Trade name: SmartStart™ Air/Water and Suction Valves
Common/Usual Name: Single Use Air/Water and Suction Valves

## 4. Device Classification

Regulation Number: 21CFR § 876.1500
Regulation Name: Endoscope and Accessories
Classification: 2
Product Code: ODC
Committee: Gastroenterology/Urology

## 5. Indications for Use

The SmartStart™ air/water valve is intended be used to control the air/water function on an endoscope during a GI endoscopic procedure.

The SmartStart™ suction valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.

## 6. Device Description

The device is intended for single-use, and is supplied sterile. Sterile, single-use air/water and suction valves help prevent potential safety risks and eliminate the need for manual cleaning and reprocessing. These valves easily incorporate into infection prevention policies as a single patient use item. The air/water valve is designed to be attached to the air/water port of the endoscope and the suction valve to the suction port of the endoscope. The activation of the suction valve allows the user to aspirate excess fluids or other debris obscuring the endoscopic image, while the activation of the air/water valve allows the user to control air and water flow to assist in cleansing the lens during procedures.

# 7. Substantial Equivalence

## 7.1 Predicate devices

The SmartStart™ Air/Water and Suction Valves are equivalent in function, intended use and scientific technology to its predicate devices, the DEFENDO Disposable Air/Water Valve K102409 and DEFENDO Disposable Suction Valve K102581.

## 7.2 Technical Characteristics

The valves are advanced into the corresponding air/water and suction cylinder until a snap is felt to ensure attachment. Once the air/water and suction valves are installed, air can be introduced through the biopsy channel of the endoscope by covering the air/water button located on the head of the endoscope. Water can be introduced to assist in cleansing the lens by depressing the air/water button located on the head of the endoscope. Suction can be applied to remove debris and fluid by depressing the suction button located on the head of the endoscope.

## 7.3 Performance Characteristics

The steps for operator use of each of the devices are equivalent to the predicates. The instructions for use describe how to use the device with a standard endoscope.

## 7.4 Substantial Equivalence Table

| **Substantial Equivalence Comparison- Suction Valve** | | | |
|---|---|---|---|
| **Device Parameters** | **EndoChoice Disposable Suction Valve** | **DEFENDO Disposable Suction Valve K102581** | **Substantial Equivalence** |
| **Product Code** | *ODC* | *ODC* | *Identical* |
| **Regulation No.** | *21CFR § 876.1500* | *21CFR § 876.1500* | *Identical* |
| **Classification** | *2* | *2* | *Identical* |
| **Manufacturer** | *EndoChoice, Inc.* | *Medivators, Inc., a Cantel Medical Company* | *NA* |
| **Supplied Sterile** | *Yes* | *Yes* | *Identical* |
| **Single use** | *Yes* | *Yes* | *Identical* |
| **Compatibility** | *Olympus 160/180/190 series endoscopes* | *Olympus and Pentax 90 Series GI Endoscopes* | *Similar* |
| **Indications for use** | *The SmartStart™ suction valve is intended to be used to control the suction function on an endoscope during a GI endoscopic procedure.* | *The DEFENDO Disposable Suction Valve is intended to be used to control the suction function of an endoscope during a GI endoscopic procedure.* | *Identical* |
| **Packaging** | *Suction and air/water valves are housed in a single tray and packaged in a sealed Tyvek pouch* | *Suction and air/water valves are housed in a single tray and packaged in a sealed Tyvek pouch* | *Identical* |
| **Substantial Equivalence Comparison- Air/Water Valve** | | | |

| Device Parameters | EndoChoice Disposable Air/Water Valve | DEFENDO Disposable Air/Water Valve K102409 | Substantial Equivalence |
|---|---|---|---|
| **Product Code** | *ODC* | *ODC* | *Identical* |
| **Regulation No.** | *21CFR § 876.1500* | *21CFR § 876.1500* | *Identical* |
| **Classification** | *2* | *2* | *Identical* |
| **Manufacturer** | *EndoChoice, Inc.* | *Medivators, Inc., a Cantel Medical Company* | *NA* |
| **Supplied Sterile** | *Yes* | *Yes* | *Identical* |
| **Single use** | *Yes* | *Yes* | *Identical* |
| **Compatibility** | *Olympus 160/180/190 series endoscopes* | *Olympus 140/160/180/240/260 series endoscopes* | *Similar* |
| **Indications for use** | *The SmartStart™ air/water valve is intended be used to control the air/water function on an endoscope during a GI endoscopic procedure.* | *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.* | *Identical* |
| **Packaging** | *Suction and air/water valves are housed in a single tray and packaged in a sealed Tyvek pouch* | *Suction and air/water valves are housed in a single tray and packaged in a sealed Tyvek pouch* | *Identical* |

# 8. Non-Clinical testing

## 8.1 Sterilization and Shelf-Life

The SmartStart™ Air/Water and Suction Valves are sterilized by Ethylene Oxide.
Validation has been completed in accordance with the following standards:

- AAMI TIR 16: 2009 Microbiological aspects of ethylene oxide sterilization. 2ed
- ANSI/AAMI/ISO 11135: 2014 Sterilization of Health-Care Products – Ethylene Oxide – Requirements for the Development, Validation and Routine Control of Sterilization Process for Medical Devices, 1ed
- ANSI/AAMI/ISO 11135-1:2007 Sterilization of Health-Care Products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. 4ed
- ANSI/AAMI/ISO 10993-7:2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals, 3ed
- AAMI TIR 14:2009 Contract sterilization using ethylene oxide, 2ed

The shelf life of the SmartStart™ Air/Water and Suction Valves is 1 year from the date of manufacture.

## 8.2 Biocompatibility

Biocompatibility which includes Cytotoxicity, Sensitization and Irritation testing for this device has been completed and passed all acceptance criteria.

## 8.3 Performance Testing

Results from various performance testing indicate that the SmartStart™ Air/Water and Suction Valves function as intended. Performance test results indicate that Air/Water and Suction Valves will perform in accordance with the acceptance criteria for air flow, water flow and leakage.

## 9. Conclusion

Based on the above information, the SmartStart™ Air/Water and Suction Valves are substantially equivalent to the predicate devices listed above. The information contained in this submission supports the fact that the SmartStart™ Air/Water and Suction Valves are as safe and effective as the predicate devices.