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

September 17, 2015

Medivators, Inc.
% Ms. Kinnari Shah
Sr. Regulatory Affairs Specialist
14605 28th Ave N
Minneapolis, MN 55447

Re: K151522
Trade/Device Name: DEFENDO Disposable Suction Valve
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: KTI
Dated: "August 21, 2015"
Received: August 20, 2015

Dear Ms. Kinnari Shah:

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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental 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)*
K151522

Device Name
DEFENDO Disposable Suction Valve

Indications for Use *(Describe)*

The DEFENDO Disposable Suction Valve is intended to be used to control the suction function of a compatible bronchoscope during a pulmonary 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

MEDIVATORS
A Cantel Medical Company

Indications for Use

510(k) number (if known): K151522

Device Name: **DEFENDO Disposable Suction Valve**

Indications for Use:

The DEFENDO Disposable Suction Valve is intended to be used to control the suction function of a compatible bronchoscope during a pulmonary procedure.

Prescription Use __X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-the-Counter Use_____ (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

MEDIVATORS
A Cantel Medical Company

510(k) Summary

Manufacturer: Medivators Inc., a Cantel Medical Company

Address: 3150 Pollock Drive,
Conroe, TX 77303
(800) 328-3345

Official Contact: Kinnari Shah
Sr. Regulatory Affairs Specialist, Medivators Inc.

Date Prepared: August 21, 2015

Trade Name: **DEFENDO Disposable Suction Valve**
Common Name: Bronchoscope Accessory
Classification Name: Bronchoscope (flexible or rigid) and accessories
Product Code: KTI
Device Class: II
Regulation No: 874.4680

Medivators Inc. has supplied the following information to support substantial equivalence of the DEFENDO Disposable Suction Valve to other Suction Valves currently cleared for sale in the United States of America.

1. **Intended Use**
   The DEFENDO Disposable Suction Valve is intended to be used to control the suction function of a compatible bronchoscope during a pulmonary procedure.

2. **Device Description**
   The subject device is a sterile, single use, disposable medical device. It is designed to be attached to the suction port of a bronchoscope during a pulmonary procedure to help the user engage in the suction function of the bronchoscope by depressing/activating the valve. The activation of the suction valve allows the user to control the suction flow of fluids from the patient to a suction pump/waste canister.

3. **Comparison to Other Devices in Commercial Distribution Within the United States**
   DEFENDO Disposable Suction Valve is equivalent in function, intended use and scientific technology to its predicate devices - Olympus Disposable Suction Valve cleared under 510(k) – K920025 and Defendo Disposable Suction Valve cleared under 510(k) – K102581.

   Similarities between Subject and Predicate Devices - Subject and predicate devices have similar intended use, principle of operation and scientific technology. They are provided sterile and must be disposed after a single use. The subject device and the predicate device –

Olympus Disposable Suction Valve have the same valve body (subcomponent of valve that mates with the endoscope) geometry and thus are compatible with the same bronchoscope models.

Difference between Subject and Predicate Devices - The only critical difference between the subject device and the predicate device – Olympus Disposable Suction Valve is the material of construction. However subject device has the same material of composition as its other predicate - Defendo Disposable Suction Valve cleared under 510(k) – K102581. When used as indicated, the subject device will not contact the patient either directly or indirectly.

A device comparison table which supports substantial equivalence of the subject device is provided below:

Table 2 – Device Comparison Table

Device Parameters	**Subject Device – DEFENDO Disposable Suction Valve**	**Predicate Device – Olympus Disposable Suction Valve (K920025)**	**Predicate Device – DEFENDO Disposable Valve (K102581)**
Trade Name	DEFENDO Disposable Suction Valve	Olympus Disposable Suction Valve	DEFENDO Disposable Suction Valve
Regulation Number	874.4680	874.4680	876.1500
Device Class	Class II	Class II	Class II
Certification Panel	Ear, Nose & Throat	Ear, Nose & Throat	Gastroenterology/Urology
Product Code	KTI	EOQ	ODC
Indication of Use	The DEFENDO Disposable Suction Valve is intended to be used to control the suction function of a compatible bronchoscope during a pulmonary procedure.	The OLYMPUS DISPOSABLE SUCTION VALVE is an attachment for Olympus bronchoscopes. The device is designed to fit into the suction port of the endoscope to insure the control and proper flow of liquids (body fluids) through the scope without leakage.	The DEFENDO Disposable Suction Valve is intended to be used to control the suction function of an endoscope during a GI endoscopic procedure.
Compatible Endoscopes	Compatible bronchoscopes	OLYMPUS® bronchoscopes	GI Endoscopes
Single Use	Yes	Yes	Yes
Supplied sterile	Yes	Yes	Yes

4. Summary of Non-Clinical Performance Data

Medivators has conducted the following testing to demonstrate substantial equivalence of DEFENDO Disposable Suction Valve–

- Design Verification Comparison Tests to Predicate Device
  - Valve Connection Test
  - Valve Depression Force Test
  - Suction Flow Test
- Shelf-life validation
  - Functional Testing
  - Dye Penetration Testing
  - Peel Strength Testing
  - Visual Seal Inspection
- Sterilization validation

5. Conclusion

Medivators Inc. has provided appropriate premarket notification information in the form of this 510(k) to support the substantial equivalence of the subject device to legally marketed predicate devices. The information and performance data provided indicates that the subject device is as safe and as effective as its predicate devices for its intended use when used in accordance with the device labeling.