December 30, 2019

Zhejiang Chuangxiang Medical Technology Co., LTD.
Lucius Long
RA Manager
301B, No.22, XinYan Road
Hanzhou, Zhejiang 311100
CHINA

Re: K192258
Trade/Device Name: Disposable Valve Sets
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODC, OCX
Dated: August 21, 2019
Received: November 26, 2019

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 control’s provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.


For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Acting Assistant Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Indications for Use

Disposable Valve Sets includes either one air/water and suction valve or one air/water, suction and biopsy valve.

Disposable Air/Water Valve
This device intended to be fitted to an endoscope air/water channel to enable the operator to control inflow of medical gases and water, whilst preventing backflow during a GI Endoscopic procedure.

Disposable Suction Valve
The device intended to be fitted to an endoscope suction channel to enable the operator to control suction whilst preventing inflow of air during a GI Endoscopic procedure.

Disposable Biopsy Valve
This device is intended to be fitted to an endoscope biopsy port to enable access for/exchange of endoscopic devices while maintaining insufflation and minimizing leakage of bio material during an 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.*

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
PRASStaff@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."
Section 8 510(k) Summary (21CFR 807.92)

1. Submitter’s information
Name: Zhejiang Chuangxiang Medical Technology Co., LTD.

Address: 301B, No.22, XinYan Road Yuhang Economic And Technological Development Zone Hangzhou Zhejiang China

Contact person: Lucius.Long
Telephone: 86-571-89167088
Fax: 86-571-89167086

2. Date of Submission
Dec. 24, 2019

3. Device

Trade/Device Name: Disposable Valve Sets
Regulation name: Endoscope and accessories
Regulation class: II
Regulation number:876.1500
Panel: Gastroenterology/Urology
Product code: ODC, OCX

4. Predicative device
4.1) 510(k) Number: K181509,
Device Name: Endorate™ Valve Sets

5. Device description
Disposable Valve Sets includes either one air/water and suction valve or one air/water, suction and biopsy valve, So we divided into two models for these devices. One suction valve, air/water valve and biopsy valve means model B, one suction valve and air/water valve means model A. These devices are supplied sterile. These valves easily incorporate into infection prevention policies as a single use item, and these valves are suitable for Olympus 140/160/180/190/240/260 series endoscopes. The following table shows the details information on the model.
### Model Specifications

<table>
<thead>
<tr>
<th>Model</th>
<th>Specification</th>
<th>ENDOSCOPIC COMPATIBILITY</th>
<th>Sterilization (Y/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>MD-A-AW01</td>
<td>Olympus</td>
<td>Y</td>
</tr>
<tr>
<td>B</td>
<td>MD-B-AW02</td>
<td>140/160/180/190/240/260</td>
<td>Y</td>
</tr>
</tbody>
</table>

### 6. Indications for use

Disposable Valve Sets includes either one air/water and suction valve or one air/water, suction and biopsy valve.

**Disposable Air/Water Valve**
This device intended to be fitted to an endoscope air/water channel to enable the operator to control inflow of medical gases and water, whilst preventing backflow during a GI Endoscopic procedure.

**Disposable Suction Valve**
The device intended to be fitted to an endoscope suction channel to enable the operator to control suction whilst preventing inflow of air during a GI Endoscopic procedure.

**Disposable Biopsy Valve**
This device is intended to be fitted to an endoscope biopsy port to enable access for/exchange of endoscopic devices while maintaining insufflation and minimizing leakage of bio material during an endoscopic procedure.
7. Technological Characteristics
The following tables are summaries of the proposed device’s technological characteristics as compared to the predicate devices.

Table 7.1 comparison of Disposable Air/Water Valve

<table>
<thead>
<tr>
<th>Item</th>
<th>Proposed device</th>
<th>Predicate device</th>
<th>Comparison to Predicate Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device name</td>
<td>Disposable Air/Water Valve</td>
<td>Andorate Disposable Air/Water Valve</td>
<td>/</td>
</tr>
<tr>
<td>510(k) number</td>
<td>/</td>
<td>K181509</td>
<td>/</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Zhejiang Chuangxiang Medical Technology Co., LTD.</td>
<td>Smardata Suzhou Co., Ltd</td>
<td>/</td>
</tr>
<tr>
<td>Product Code</td>
<td>ODC</td>
<td>ODC</td>
<td>Same</td>
</tr>
<tr>
<td>Regulation No.</td>
<td>876.1500</td>
<td>876.1500</td>
<td>Same</td>
</tr>
<tr>
<td>Class</td>
<td>II</td>
<td>II</td>
<td>Same</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>This device intended to be fitted to an endoscope air/water channel to enable the operator to control inflow of medical gases and water, whilst preventing backflow during a GI Endoscopic procedure.</td>
<td>The ENDORATE™ Disposable Air/Water valve is intended to be used control the air/water function of an endoscope during a GI Endoscopic procedure.</td>
<td>Substantial Equivalence</td>
</tr>
<tr>
<td>Supplied Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Same</td>
</tr>
<tr>
<td>Sterilization method</td>
<td>EO</td>
<td>EO</td>
<td>Same</td>
</tr>
<tr>
<td>Single Use</td>
<td>Yes</td>
<td>Yes</td>
<td>Same</td>
</tr>
<tr>
<td>Packaging</td>
<td>Suction, air/water and/or biopsy valves are housed in a single tray and packaged in a sealed pouch</td>
<td>Suction, air/water, biopsy valves are housed in a single tray and packaged in a sealed pouch</td>
<td>Substantial Equivalence</td>
</tr>
<tr>
<td>Shelf Life</td>
<td>Three years</td>
<td>Three years</td>
<td>Substantial Equivalence</td>
</tr>
</tbody>
</table>
### Table 7.2 comparison of Disposable Suction Valve

<table>
<thead>
<tr>
<th>Item</th>
<th>Proposed device</th>
<th>Predicate device</th>
<th>Comparison to Predicate Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device name</td>
<td>Disposable Suction Valve</td>
<td>Endorate™ Disposable Suction Valve</td>
<td>/</td>
</tr>
<tr>
<td>510(k) number</td>
<td>/</td>
<td>K181509</td>
<td>/</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Zhejiang Chuangxiang Medical Technology Co., LTD.</td>
<td>Smardata Suzhou Co., Ltd</td>
<td>/</td>
</tr>
<tr>
<td>Product Code</td>
<td>ODC</td>
<td>ODC</td>
<td>Same</td>
</tr>
<tr>
<td>Regulation No.</td>
<td>876.1500</td>
<td>876.1500</td>
<td>Same</td>
</tr>
<tr>
<td>Class</td>
<td>II</td>
<td>II</td>
<td>Same</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>The device intended to be fitted to an endoscope suction channel to enable the operator to control suction whilst preventing inflow of air during a GI Endoscopic procedure.</td>
<td>The ENDORATE™ Disposable Suction valve is intended to be used control the suction function of an endoscope during a GI Endoscopic procedure.</td>
<td>Substantial Equivalence</td>
</tr>
<tr>
<td>Supplied Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Same</td>
</tr>
<tr>
<td>Sterilization method</td>
<td>EO</td>
<td>EO</td>
<td>Same</td>
</tr>
<tr>
<td>Single Use</td>
<td>Yes</td>
<td>Yes</td>
<td>Same</td>
</tr>
<tr>
<td>Packaging</td>
<td>Suction, air/water and/or biopsy valves are housed in a single tray and packaged in a sealed pouched</td>
<td>Suction, air/water, biopsy valves are housed in a single tray and packaged in a sealed pouched</td>
<td>Substantial Equivalence</td>
</tr>
<tr>
<td>Shelf Life</td>
<td>Three years</td>
<td>Three years</td>
<td>Substantial Equivalence</td>
</tr>
</tbody>
</table>
### Table 7.3 comparison of Disposable Biopsy Valve

<table>
<thead>
<tr>
<th>Item</th>
<th>Proposed device</th>
<th>Predicate device</th>
<th>Comparison to Predicate Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device name</td>
<td>Disposable Biopsy Valve</td>
<td>Endorate™ Disposable biopsy Valve</td>
<td>/</td>
</tr>
<tr>
<td>510(k) number</td>
<td>/</td>
<td>K181509</td>
<td>/</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Zhejiang Chuangxiang Medical Technology Co., LTD.</td>
<td>Smardata Suzhou Co., Ltd</td>
<td>/</td>
</tr>
<tr>
<td>Product Code</td>
<td>OCX</td>
<td>OCX</td>
<td>Same</td>
</tr>
<tr>
<td>Regulation No.</td>
<td>876.1500</td>
<td>876.1500</td>
<td>Same</td>
</tr>
<tr>
<td>Class</td>
<td>II</td>
<td>II</td>
<td>Same</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>This device is intended to be fitted to an endoscope biopsy port to enable access for/exchange of endoscopic devices while maintaining insufflation and minimizing leakage of bio material during an endoscopic procedure.</td>
<td>The Endorate™ Disposable biopsy valve is intended to cover the endoscope biopsy port during an endoscopy procedure. In addition, the valve provides access for endoscopic device passage and exchange, helps maintain insufflation and minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure.</td>
<td>Substantial Equivalence</td>
</tr>
<tr>
<td>Supplied Sterile</td>
<td>Sterile</td>
<td>Sterile</td>
<td>Same</td>
</tr>
<tr>
<td>Sterilization method</td>
<td>EO</td>
<td>EO</td>
<td>Same</td>
</tr>
<tr>
<td>Compatibility</td>
<td>Olympus 140/160/180/190/240/260 series endoscopes</td>
<td>Olympus® / Fujinon® and Pentax® Endoscopes</td>
<td>Substantial Equivalence</td>
</tr>
<tr>
<td>Single Use</td>
<td>Yes</td>
<td>Yes</td>
<td>Same</td>
</tr>
<tr>
<td>Packaging</td>
<td>Suction, air/water and/or biopsy valves are housed in a single tray and packaged in a sealed pouch</td>
<td>Suction, Air/Water, biopsy valves are housed in a single tray and packaged in a sealed pouch. Non Sterile Biopsy valve is</td>
<td>Substantial Equivalence</td>
</tr>
</tbody>
</table>
also sold individually packaged in a sealed pouch. Biopsy valve is either in blue or black depending on the availability.

| Shelf Life | Three years | Three years | Substantial Equivalence |

8. Performance data

In-vitro Testing has been performed and all components, subassemblies, and/or full devices met the required specifications for the completed tests. A summary of the test results has been provided for:

**Disposable Suction Valve**

1. Endoscope Compatibility
2. Vacuum Leak Test
3. Suction Flow Test
4. Depression Force Test

**Disposable Air/Water Valve**

1. Endoscope Compatibility
2. Water Flow Test
3. Air Flow Test
4. Leak Test
5. Depression Force Test

**Disposable Biopsy Valve**

1. Endoscope Compatibility
2. Leak Test
3. Squeegee Leak Test

The EO residual was measured after sterilization of the device to meet the criteria defined in ISO 10993-7 Second Edition 2008-10-15.

The EO sterilization cycle has a Sterility Assurance Level (SAL) of $10^{-6}$.

The shelf-life for three years had been validated in accelerated testing according to ASTM F1980-16 (2016) and the requirements on packaging for terminally sterilized medical device per ISO 11607-1 First Edition 2006-04-15 and ISO 11607-2 First Edition 2006-04-15 are also met. The testing successfully demonstrated essential performance is achieved before and after the shelf life test.

Biocompatibility testing was performed in accordance with the FDA Guidance, “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process’ issued on June 16, 2016. The cytotoxicity, sensitization and intracutaneous irritation test were performed to demonstrate the biocompatibility of the device.
9. Non-Clinical Testing:
The device has undergone both bench testing of performance and laboratory biocompatibility testing for cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity and pyrogen test in accordance with 21 CFR, Part 58. The Disposable Valve Sets 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.

10. Conclusions

Chuangxiang medical has demonstrated that the proposed device Disposable Valve Sets is substantially equivalent to Smardata Suzhou Co., Ltd. currently marketed Endorate™ Valve Sets (K181509).