DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 25, 2017

Shenyang Shenda Endoscope Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 China

Re: K161298
Trade/Device Name: Shenda Sinuscope
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: July 26, 2017
Received: July 27, 2017

Dear Diana Hong:

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,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K161298

Device Name
ShenDa® Sinuscope

Indications for Use *(Describe)*
ShenDa® Sinuscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx.

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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510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K161298

1. Date of Preparation: 08/24/2017

2. Sponsor Identification

Shenyang Shenda Endoscope CO., LTD.
No.123 Hezuo Street, Dadong District,
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Lee Fu (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: ShenDa® Sinuscope
Common Name: Sinuscope
Model: BD-1
19 Product Codes: J0200G, J0200CG, J1200, J2200, J0212, J0230G, J0230CG, J1230, J2230, J0245G, J0245E, J0270G, J0270CG, J1270, J2270, J0290E, J0200E, J0230E, and J0270E

Regulatory Information
Classification Name: Nasopharyngoscope (Flexible or Rigid)
Classification: Class II
Product Code: EOB
Regulation Number: 21 CFR part 874.4760
Review Panel: Ear Nose & Throat

Intended Use Statement:
ShenDa® Sinuscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx.

Device Description
ShenDa® Sinuscope is an unchanneled endoscope intended to provide an endoscopic means to view the nasal cavity and nasopharynx.

The endoscope is available in the various combination of outer diameter (2.7mm, 3mm, 4mm) and vision direction angles (0, 12, 30, 45, 70 and 90 degree), which are listed in Table 1 Specifications of the Proposed Device of this document.

It can be connected to OLYMPUS light source and OLYMPUS light cable; the information of associated OLYMPUS compatible equipments is provided as following:

Light source	OLYMPUS CLV-180 EVIS EXTRA II XENON LIGHT SOURCE (K100584)
Light-guide cable	Size S, plug type, 3m, CF type, identification number: WA03200A (K944072)
Connector	Not required

It is a reusable device subject to cleaning and steam sterilization.

Table 1 Specifications

No.	Code	Direction of view (°)	Field of view field (°)	Diameter of inserting section(Φ)	Working length(mm)
1	J0200G	0	90	4	175
2	J0200CG	0	110	4	175
3	J1200	0	60	3	175
4	J2200	0	60	2.7	175
5	J0212	12	60	4	175
6	J0230G	30	90	4	175
7	J0230CG	30	110	4	175
8	J1230	30	60	3	175
9	J2230	30	60	2.7	175
10	J0245G	45	90	4	175
11	J0245E	45	60	4	175
12	J0270G	70	90	4	175
13	J0270CG	70	110	4	175
14	J1270	70	60	3	175
15	J2270	70	60	2.7	175
16	J0290E	90	60	4	175
17	J0200E	0	60	4	175
18	J0230E	30	60	4	175
19	J0270E	70	60	4	175

5. Identification of Predicate Device

510(k) Number: K965233
Device Name: SHARPSITE Ac
Manufacturer: Medtronic Xomed Inc.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1-2005, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2007, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests.
- IEC 60601-2-18:2009, Medical Electrical Equipment- Part 2: Particular requirements for the basic safety and essential performance of endoscopic equipment.

- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro Cytotoxicity;
- ISO 10993-10:2010, Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization;
- ISO 8600-1:2015 Endoscopes--Medical endoscopes and Endotherapy Devices--part 1: General Requirements.
- ISO 8600-5:2005 Optics and photonics-Medical endoscopes and endotherapy devices part 5: Determination of optical resolution of rigid endoscopes with optics

The performance test items include the insertion portion width, field of view and direction of view, and optical resolution.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 SE Comparison

Item	Proposed Device	Predicate Device K965233
Product Code	EOB	EOB
Regulation Number	21 CFR part 874.4760	21 CFR part 874.4760
Intended Use	ShenDa® Sinuscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx.	The Xomed SHARPSITE Ac rigid rod lens endoscopes are intended for use in surgical imaging in otolaryngology and Head and Neck procedures, including rhinology, and endoscopic plastic and reconstructive surgery.
Feature	unchanneled rigid endoscope	unchanneled rigid endoscope
Mechanism	Viewing Optics	Viewing Optics
Working Length	175mm	175mm
Direction of View	0, 12, 30, 45, 70, and 90 degree	0, 30, and 70 degree
Field of View	60, 90 and 110 degress	100 and 102 degress
Shaft Body diameter	2.7, 3.0, 4.0mm	4.0mm
Depth of Field	1-50mm	Not Known
Safety	Comply with IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-18	Not Known
Biocompatibility	Comply with ISO 10993-5 and ISO 10993-10	Not Known
	No adverse reaction demonstrated in cytotoxicity, intracutaneous and skin sensitization	Not Known
Reprocessing	Cleaning and Steam Sterilization,	Cleaning and Steam Sterilization,

Although the indications for use are expressed differently, the proposed device and predicate device have the similar product structure, working principle and optical performance. This item is considered to be substantially equivalent.

The proposed device provides a more range of field of view and direction of view than the predicate device, additionaly it provides more options of diameters of shaft than the predicate device, to the physicians to fit various patients, these difference it will not affect the safety and effectiveness concerning the SE. Although the depth of filed of the prediate device is unknow, we think the design of the depth of field of the proposed device is appropriate for the clinical use. Although the result of Electrical Safety, EMC and biocompatibility of predicate device is unknown, it is concluded from the relevant testng results of the proposed device, that the proposed device is safe and effective.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.