January 14, 2022

Well Lead Medical CO., LTD.
Caroline Gong
RA Specialist
No. 47 Guomao Avenue South, Hualong, Panyu
Guangzhou, Guangdong 511434
China

Re: K211814
Trade/Device Name: Endoscopic Seal
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: ODC
Dated: December 10, 2021
Received: December 14, 2021

Dear Caroline Gong:

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. 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.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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,

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K211814

Device Name
Endoscopic Seal

Indications for Use *(Describe)*
Endoscopic Seal is a self-sealing cap that is intended to prevent the backflow of fluid through the working channel of an endoscope.

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

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

- 510(k) Owner's Name: Welllead Medical CO., LTD
- Address: No.47, Guomao Avenue South, Hualong, Panyu, Guangzhou, China 511434
- Tel: 86 20 8475 8878-6531
- Contact Person (including title): Ms. Caroline Gong (RA Specialist)
- E-mail: gongyoushan@welllead.com.cn

2. Subject Device Information

- Type of 510(k) submission: Traditional
- Common Name: Endoscopic Seal
- Trade Name: Wellead Endoscopic Seal
- Device: Endoscope Channel Accessory
- Regulation Description: Endoscope and accessories
- Regulation Medical Specialty: Gastroenterology/Urology
- Review Panel: Gastroenterology/Urology
- Product Code: ODC
- Regulation Number: 876.1500
- Regulation Class: 2

3. Predicate Device Information

Sponsor	OBP Corporation
Device Name	OBP Self-Sealing Endoscopic Seal with Luer Lock
510(k) Number	K091838
Product Code	HIH, ODC, HET

Regulation Number	21 CFR 876.1500 and 884.1690
Regulation Class	2

4. Device Description

The Endoscopic Seal is mounted to the proximal port of the endoscope working channel and intended to resist the backflow of distention fluid when the channel is not being used or when instruments are passed through the working channel.

The Endoscopic Seal consists of a silicone seal, an introducer, and an adapter with sealing ring (optional).The Introducer is used to enable improved access during endoscopic procedures. The Adapter and Sealing Ringare optional for Endoscopic Seal. They are used with the non-standard Luer endoscopes.

The silicone seal combined with introducer can be used with all endoscopes with the proximal port of the working channel between 6 mm to 9 mm in its largest outside diameter. Mount the silicone seal onto the working channel of the Endoscope. Make sure the connection is tight. Insert the introducer into the silicone seal.If using the WOLF endoscope, mount the adapter with sealing ring onto the endoscope working channel port first and then place the silicone seal and introducer onto the adapter.

5. Indications for Use

Endoscopic Seal is a self-sealing cap that is intended to prevent the backflow of fluid through the working channel of an endoscope..

6. Test Summary

Endoscopic Seal has been evaluated the safety and performance by lab bench testing as following:

- ASTM F1929 Standard Test Method for Detecting Seal Leaks in Po-rous Medical Packaging by Dye Penetration
- ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials

- ASTM F1886 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO 80369-20: 2015 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods
- ISO 10993-1:2018 Biological Evaluation of Medical Devices - Part 1: Eval-uation And Testing Within A Risk Management Process
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11: 2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

7. Comparison to predicate device and conclusion

Elements of Comparison	Subject Device	Predicate Device	Remark
Device Name and Model	Endoscope Seal (Type: I)	OBP Self-Sealing Endoscopic Seal with Luer Lock	--
510 (K) Number	Applying	K091838	--
Regulation number	21 CFR 876.1500	21 CFR 876.1500 and 884.1690	SE
Regulation description	Endoscope and accessories	Endoscope and accessories	SE
Product code	ODC	HIH, ODC, HET	SE
Class	II	II	SE
Indication for Use	Endoscopic Seal is a self-sealing cap that is intended to prevent the backflow of fluid through the working channel of an endoscope.	The OBP Self-Sealing Endoscopic Seal is a single use, sterile endosopic introducer seal. It is afficed to the proximal port of the endoscope working channel. It prevents efflux of distention	SE

Elements of Comparison	Subject Device	Predicate Device	Remark
		fluid when the channel is not being used or when instruments are passed through the working channel of the endoscope. The seal may be used with following types of endoscopes: ● Hysteroscope ● Laparoscope ● Cystoscope ● Colonoscope	
Prescription use	Yes	Yes	SE
Sterility	Sterile	Sterile	SE
Use	Single Use	Single Use	SE
Model	Type I	The 4 different seals are marked with different colored bands: yellow (0.6mm seal), light pink (1.2mm seal), green (1.6mm seal), and blue (2.0mm seal).	SE
Materials of Endoscopic Seal	Silicone	Silicone	SE
Materials of Components	Introducer (POM), Adapter (PC), Sealing Ring (Silicone)	N/A	SE
Components	Introducer, Adapter, Sealing Ring	N/A, predicate device has funnel guided entry and Luer-Lock fitting.	
Performance test result			
Fastness of connection	Identical to predicated device	Predicate device is tested together with subject device	SE
Smoothness	Identical to predicated device		
Sealing performance (Leakage)	Identical to predicated device		

Elements of Comparison	Subject Device	Predicate Device	Remark
Biocompatibility	Cytotoxicity test - ISO 10993-5: 2009, Sensitization - ISO 10993-10:2010, Skin irritation - ISO 10993-10:2010 Material-Mediated Pyrogenicity – ISO 10993-11: 2017 Acute Systemic Toxicity – ISO 10993-11: 2017	Unknown	

Comparison in Detail(s):

The description of indication for use for subject device is different from predicate device. However, both of them are indicated to resist the backflow of fluid around an instrument inserted through the working channel. Therefore, this difference does not affect substantially equivalence.

Although the materials of subject device is different from predicate device, we can find that the subject devices all meet the requirements of ISO 10993-5, ISO 10995-10, ISO 10993-11. So the differences of the materials will not raise any safety or effectiveness concern.

Finial Conclusion:

The technological characteristics, features, specifications, materials, and indication for use of Endoscopic Seal is substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

8. Date of the summary prepared: January 7, 2022