December 20, 2024

Leo Medical Co., Ltd.
℅ Diana Hong
Official Correspondent
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, Shanghai 200120
China

Re: K241888
Trade/Device Name: Single-use Balloon Dilatation Catheter
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: FGE
Dated: November 25, 2024
Received: November 25, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Anthony Lee -S

Anthony Lee, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
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Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241888

Device Name

Single-use Balloon Dilatation Catheter

Indications for Use *(Describe)*

This device is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the gastrointestinal tract. It is also indicated in adults for endoscopic dilatation of Sphincter of Oddi with or without prior sphincterotomy.

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.

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K241888

1. Date of Preparation: 06/21/2024

2. Sponsor Identification

Leo Medical Co., Ltd.
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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Single-use Balloon Dilatation Catheter
Common Name: Biliary catheter and accessories

Regulatory Information
Classification Name: stents, drains and dilators for the biliary ducts
Classification: II,

Product Code: FGE,
Regulation Number: 21 CFR 876.5010,
Review Panel: Gastroenterology/Urology

Indications for Use
This device is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the gastrointestinal tract. It is also indicated in adults for endoscopic dilatation of Sphincter of Oddi with or without prior sphincterotomy.

Device Description
According to the structure of the device, it can be divided into three types, RX type, OTW type and OTW with Stainless Wire-guided type. The Rx proposed device mainly consists of tip, balloon, marker band, shaft, sleeve, stress diffusion tube and hub. The OTW proposed device mainly consists of tip, balloon, marker band, shaft, stress diffusion tube and hub. The structure of the OTW with Stainless Wire-guided model same with the structure of OTW model. The difference between OTW with Stainless Wire-guided type catheter and OTW type catheter is that OTW with Stainless Wire-guided type catheter is preloaded with a guide wire and a guide wire locking component. The difference between the RX type catheter and the OTW series catheter is that the guidewire exit position is different. The guide wire of OTW series catheter passed through the guide wire lumen of the catheter. The guidewire of the Rx type catheter will pass through the guidewire exchange port on the shaft.

Single-use Balloon Dilatation Catheter is divided into different specifications. Shafts are available in two different diameters. The effective length of the catheter is 180cm and 240cm. Balloon diameters are available in six different diameters 6-7-8mm, 8-9-10 mm, 10-11-12 mm, 12-13.5-15 mm, 15-16.5-18 mm, 18-19-20 mm, and the balloon lengths are available in 30 mm,55 mm and 80 mm three different length.

5. Identification of Predicate Devices and Reference Device

Predicate Device 1
510K Number: K112994
Trade Name: CRE Dilatation Balloon

Predicate Device 2
510K Number: K172520
Trade Name: CRE™ RX Biliary Balloon Dilatation Catheter

Reference device
510K Number: K122924
Trade Name: CRE Fixed Wire Balloon Dilatation Catheter

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:

- ISO 10993-7:2008 Biological Evaluation Of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals
- ISO 10993-5:2009 Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2021 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
- ISO 10993-23:2021 Biological evaluation of medical devices — Part 23: Tests for irritation.
- ASTM F88/F88M-21 Standard test method for seal strength of flexible barrier materials
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems
- USP<151> Pyrogen Test
- ISO10555-4:2013 Intravascular catheters -- Sterile and single-use catheters -- Part 4: Balloon dilatation catheters.
- ISO 10555-1:2013/A1:2017 Intravascular catheters —Sterile and single-use catheters —Part 1: General requirements.
- ISO20696:2018(E) Sterile urethral catheters for single-use.
- ASTM F640-20 Standard Test Methods for Determining Radiopacity for Medical Use
- ASTM F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- USP<85> Bacterial Endotoxins Test
- ISO 80369-7:2023 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
- ISO 80369-20:2023 Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods
- ASTM F3172 Standard Guide for Design Verification Device Size and Sample Size Selection for Endovascular Devices

The performance testing conducted on subject device and predicate device are listed below. All the test results demonstrate proposed device meet the requirements of its pre-defined acceptance criteria and intended uses.

- Dimension Test
- Appearance
- Compatibility Test
- Delivery and Retrieval Force

- Peak Tensile Force
- Burst Pressure
- Kink Stability
- Corrosion Resistance Test
- Air Leakage
- Liquid Leakage
- Luer connector
- Radiopacity
- Balloon Burst Pressure
- Balloon Compliance
- Balloon Deflation Time
- Balloon Fatigue

The proposed device sterilization process using Ethylene Oxide (EO) has been validated in accordance with ISO 11135:2014 to achieve a sterility assurance level (SAL) of 10^{-6}. EO and Ethylene Chlorohydrin (ECH) residuals were below the limits specified in ISO 10993-7:2008. Bacterial Endotoxin Levels were below the level of 20 EU/device in accordance with USP <85>. Both baseline and accelerated shelf life testing were conducted demonstrating the device will perform as intended to support the proposed 3-year shelf-life.

- Package Integrity Test – after environmental conditioning, simulated transportation testing in accordance to ASTM D4169-22 on final, packaged, and sterile device.
- Sterile Barrier Packaging performed on the proposed device:
  - Visual Inspection per ASTM F1886/F1886M-16
  - Seal Strength per ASTM F88/F88-21
  - Dye Penetration per ASTM F1929-15
- Shelf-life of 3 years is validated using FDA recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

The biocompatibility evaluations were conducted in accordance with the 2020 FDA Guidance document Use of International Standard ISO-10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The cytotoxicity, sensitization, intracutaneous irritation, system toxicity and pyrogen tests were performed to demonstrate the biocompatibility of the device.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1. General Comparison

Item	Proposed Device	Predicate Device 1 K112994	Predicate Device 2 K172520	Reference Device K122924	Remark
Device Name	Single-use Balloon Dilatation Catheter	GRE Dilatation Balloon	CRE™ RX Biliary Balloon Dilatation Catheter	CRE Fixed Wire Balloon Dilatation Catheter	/
Product Code	FGE	FGE	FGE	KNQ	Same
Regulation No.	21 CFR 876.5010	21 CFR 876.5010	21 CFR 876.5010	21 CFR 876.5365	Same
Class	II	II	II	II	Same
Indications for Use	This device is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the gastrointestinal tract. It is also indicated in adults for endoscopic dilatation of Sphincter of Oddi with or without prior sphincterotomy.	The CRE™ Wireguided Balloon Dilatation Catheter is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. It is also indicated in adults for endoscopic dilatation of Sphincter of Oddi with or without prior sphincterotomy.	CRE™ RX Biliary Balloon Dilatation Catheter is indicated for use in adults for endoscopic dilatation of the Sphincter of Oddi with or without prior sphincterotomy. The CRE™ RX Biliary Balloon Dilatation Catheters may be used for injection of contrast medium for fluoroscopic visualization of the bile ducts.	The CRE™ Balloon Dilatation Catheter is intended for use in adult and adolescent populations to endoscopically dilate strictures of the esophagus.	Similar
Catheter Type	Rx, OTW, OTW (Stainless Wire-guided)	OTW(Stainless Wire-guided)	RX	OTW (Fixed wire)	Different
Components	Rx: Tip, Balloon, Marker band, Shaft, Sleeve, Stress diffusion tube, Hub	Tip, balloon, marker band, handle junction, and guidewire.	Tip, balloon, marker band and handle junction	Tip, balloon, marker band, tube and handle junction.	Different

	OTW(Stainless Wire-guided): Tip, balloon, marker band, Shaft， Sleeve， Stress diffusion tube， Hub, Guide wire locking device, Stainless Guide wire OTW: Tip, balloon, marker band, Shaft, Stress diffusion tube, Hub,				
Marker Bands Present	Yes	Yes	Yes	Yes	Same
Single Use	Single Use	Single Use	Single Use	Single Use	Same
Balloon Diameter(mm)	6-7-8, 8-9-10, 10-11-12, 12-13.5-15, 15-16.5-18, 18-19-20	6-7-8, 8-9-10, 10-11-12, 12-13.5-15, 15-16.5-18, 18-19-20	6-7-8, 8-9-10, 10-11-12, 12-13.5-15, 15-16.5-18, 18-19-20	6-7-8, 8-9-10, 10-11-12, 12-13.5-15, 15-16.5-18, 18-19-20	Same
Balloon length(mm)	30, 55, 80	55	30,55	80	Different
Working length(mm)	1800,2400	1800,2400	1800	1800	Same
Patient-contact Material					
Tip	Pebax 3533 SA01 Med	Guide head (Pebax)	Unknown	Unknown	Different

Shaft	Pebax 7233 SA01 Med	Catheter (Pebax)			
Balloon	Nylon 12 ML21	Balloon (Pebax)			
Stainless Guide wire (OTW with Stainless Wire-guided)	SUS 304	Guidewire (stainless steel)			
Sterilization					
Sterile/non-sterile:	Sterile	Sterile	Sterile	Sterile	Same
Method	EO sterilized	EO sterilized	EO sterilized	EO sterilized	Same
SAL	10^{-6}	10^{-6}	10^{-6}	10^{-6}	Same
Biocompatibility					
Cytotoxicity	No cytotoxicity	Conform with ISO 10993 standards	Conform with ISO 10993 standards	Conform with ISO 10993 standards	Same
Intracutaneous Reactivity	No intracutaneous reactivity				
Sensitization	No sensitization				
Acute System Toxicity	No acute system Toxicity				
Pyrogen	No pyrogen				

Similar - Indications for Use

The indication for use of the proposed device and the indication for use of the predicate device 1 are exactly the same. The indication for use of the proposed device and predicate device 2 are slightly different, but the intend use "*indicated in adults for endoscopic dilatation of Sphincter of Oddi with or without prior sphincterotomy.*" can be covered by predicate device 2. The clinical application site and applicable population of the proposed device can be completely covered by two predicate devices. Therefore, the similar indication for use will not affect the safety and effectiveness of the proposed device.

Different - Catheter Type

The catheter type of the proposed device is different to that of the predicate device 1 and predicate device 2. The proposed device includes Rx, OTW and OTW (Stainless Wire-guided). The Rx type catheter and OTW (Stainless Wire-guided) type catheter can be covered by the predicate device 1 and predicate device 2. The OTW type catheter is very similar to OTW (Stainless Wire-guided) catheter, and the difference with OTW (Stainless Wire-guided) catheter is only the lack of preinstalled guide wire and the structure of OTW (Stainless Wire-guided) catheter same with OTW catheter. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different – Components

The component of the proposed device is different to that of the predicate device 1 and predicate device 2. Different manufacturers have different claims on the name of the device components, the difference in the component is only the difference in the name. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Balloon length

The balloon length of the predicate device 1 is 55mm, the balloon length of the predicate device 2 is 30mm and 55mm, the 30mm and 50mm balloon length of the proposed device is same as the balloon length of the predicate device 2. The 80 mm balloon length of proposed device can be covered by the reference device. Besides, the 80 mm balloon length proposed device was tested for performance and the test results meet the acceptance criteria. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Material

The materials of the proposed device are different from those of the predicate device. The biocompatibility tests were also performed on the proposed device and the test results showed that there was no adverse effect. Therefore, this difference does not raise new safety and efficacy issues.

9. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and perform as well as or better than the legally marketed predicate device 1 K112994 and

predicate device 2 K172520.