Anrei Medical (Hangzhou) Co., Ltd
℅ Jia Huang
Senior Regulatory Affairs Specialist
Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K202987
Trade/Device Name: Rescue™ Pulmonary Grasping Forceps
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: September 28, 2020
Received: September 30, 2020

Dear Jia Huang:

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,

Brandon L. Blakely, Ph.D.
Acting Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202987

Device Name
Rescue™ Pulmonary Grasping Forceps

Indications for Use *(Describe)*
The Rescue™ Pulmonary Grasping Forceps are intended to be used to retrieve foreign body and/or excised tissue endoscopically within the upper airways and tracheobronchial tree.

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

1. Submitter:

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Contact: Huibing Yang
Director, Regulatory Affairs

Date Prepared: April 29, 2021

2. Proposed Device:

Trade Name:	Rescue™ Pulmonary Grasping Forceps
Classification Name:	Bronchoscope (flexible or rigid) and accessories
Regulation Number:	874.4680
Product Code:	EOQ
Classification:	Class II

3. Predicate Device:

Trade Name:	Olympus FG Series of Grasping Forceps
510(k) Number:	K962533
Classification Name:	Bronchoscope (flexible or rigid) and accessories
Regulation Number:	874.4680
Product Code:	EOQ
Classification:	Class II

Reference Device:	EndoChoice Grasping Forceps
Trade Name:	EndoChoice Grasping Forceps
510(k) Number:	K101298
Classification Name:	Endoscopic Grasping/Cutting Instrument, Non-Powered
Regulation Number:	876.1500
Product Code:	OCZ
Classification:	Class II

4. Proposed Device Description:

The Rescue™ Pulmonary Grasping Forceps is sterile, single-use devices. The Rescue™ Pulmonary Grasping Forceps can retrieve foreign body and/or excised tissue endoscopically within the upper airways and tracheobronchial tree.

The Rescue™ Pulmonary Grasping Forceps is composed of thumb ring, spool and sliding handle at proximal end and the middle section of the Rescue™ Pulmonary Grasping Forceps is flexible shaft with a working length of 120 cm that connects with the distal end jaw assembly with an inner jaw opening of 4.5 mm. The Rescue™ Pulmonary Grasping Forceps is designed to pass through a 2.0 mm or greater working channel of a bronchoscope.

To operate the device, the user slides the spool back and forth over the handle body to open and close the jaws. The spool simultaneously actuates the pull wire which runs the length of the device and terminates with a connection to the jaws. Using Rescue™ Pulmonary Grasping Forceps the users can grasp excised tissue or foreign body by opening and then closing the jaws. The users can then retrieve the excised tissue or foreign body by pulling the Rescue™ Pulmonary Grasping Forceps with bronchoscope out of patient.

5. Indications for Use:

The Rescue™ Pulmonary Grasping Forceps is indicated to be used to retrieve foreign body and/or excised tissue endoscopically within the upper airways and tracheobronchial tree.

6. Technological Characteristics:

The proposed Rescue™ Pulmonary Grasping Forceps has identical intended use and similar technological characteristics as the predicate Olympus FG Series Grasping Forceps (K962533).

Both the proposed Rescue™ Pulmonary Grasping Forceps and the predicate Olympus FG Series Grasping Forceps (K962533) are designed to be composed of three major sections: proximal end, flexible shaft/catheter and distal end. The proposed Rescue™ Pulmonary Grasping Forceps and the predicate Olympus FG Series Grasping Forceps (K962533) share the similar technological characteristics as shown in table below.

Technological Characteristics	**Proposed Rescue™ Pulmonary Grasping Forceps**	**Predicate Olympus FG Series Grasping Forceps (K962533)**
Jaw Style	Rat Tooth	Rath Tooth, Alligator, "W" Shape, Rubber Tipped Cups
Inner Jaw Opening	4.5 mm	3-13 mm
Maximum Insertion Portion Outer Diameter (mm)	1.8 mm	1.85-2.6 mm
Minimum Bronchoscope Working Channel	2.0 mm	2.0 mm for FG-14P-1 with Rat Tooth Grasping Jaws
Shaft Working Length	120 cm	105-190 cm

The proposed Rescue™ Pulmonary Grasping Forceps is sterile, single use while the predicate Olympus FG Series Grasping Forceps (K962533) is reusable. The proposed Rescue™ Pulmonary Grasping Forceps is sterilized using ethylene oxide sterilization and the predicate Olympus FG Series Grasping Forceps (K962533) is reprocessed using method such as autoclave.

7. Performance Data:

The proposed Rescue™ Pulmonary Grasping Forceps was evaluated via bench-top testing, biocompatibility testing and sterilization testing.

The following bench-top testing was performed on the proposed Rescue™ Pulmonary Grasping Forceps:

- Jaw opening width
- Effective working length
- Maximum insertion portion outer diameter
- Flexibility – jaws open without seizing

- Flexibility – jaw alignment
- Grasping reliability
- Compatibility with bronchoscope
- Smooth edges
- Connect strength – clevis to coil joint
- Connect strength – coil to handle joint

The proposed device passed all pre-defined testing requirements.

The Rescue™ Pulmonary Grasping Forceps was evaluated per the requirements of *ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing*. The device met the requirements of the performance standards and are considered biocompatible.

The Rescue™ Pulmonary Grasping Forceps was also evaluated per the sterilization requirements *ISO 11135:2014 Sterilization of Health Care products - Ethylene Oxide - Requirements for the Development, Validation, and Routine Control of a Sterilization processes for Medical Devices* and *ISO 10993-7 Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals*. The device met the requirements of the standards and is considered sterile.

8. Conclusion:

The proposed Rescue™ Pulmonary Grasping Forceps had passing results for the bench-top testing, biocompatibility and sterilization testing performed. The data provided by Anrei Medical (Hangzhou) Co., Ltd demonstrate that the proposed Rescue™ Pulmonary Grasping Forceps met the pre-defined design specifications and is suitable for the intended use. The data also demonstrate that the proposed Rescue™ Pulmonary Grasping Forceps is substantially equivalent to the currently marketed Olympus FG Series Grasping Forceps (K962533) and raises no new questions of safety or effectiveness.