November 20, 2017

Spiration, Inc.
Cheryl Frederick
Executive Director, Regulatory Affairs
6675 185th Avenue N.E.
Redmond, Washington 98052

Re: K171492
Trade/Device Name: B7 2C Occlusion Balloon
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: August 22, 2017
Received: August 24, 2017

Dear Cheryl Frederick:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171492

Device Name

B7-2C Occlusion Balloon

Indications for Use *(Describe)*

The B7-2C Occlusion Balloon is to be used for selective endoscopic bronchography, saline injection associated with bronchoalveolar lavage, bronchial hemostasis and airway occlusion to localize air leaks.

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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5 510(k) Summary – K171492

Submitter Information

Date of 510(k) Summary Preparation: May 19, 2017

Name and Address of Private Labeler: **Spiration, Inc.**
6675 185th Avenue NE
Redmond, WA 98052

Name and Address of Manufacturer: Aomori Olympus Co., LTD
2-248-1 Okkonoki
Kuroishi-shi Aomori
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Contact Person: Cheryl Frederick
Executive Director, RA/QA
Phone: (425) 636-5470
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Subject Device

Device Trade Name: B**7 2C Occlusion Balloon**
Common Name: Bronchoscope and Accessories

Classification Regulation: Bronchoscope (flexible or rigid) and Accessories
21 CFR 874.4680

Product Code: EOQ
Review Panel: 77- Ear, Nose and Throat

Predicate Device

Trade Name: **Olympus B7-2C**
510(k) Number: K962901
Manufacturer: Aomori Olympus Co., LTD

Device Description

Olympus Respiratory America (ORA) dba Spiration, Inc. is submitting this Traditional 510(k) premarket notification to add a modified name and modified Indication for use to for the already cleared **Olympus B7-2C Balloon Catheter** (K962901, August 20, 1996). The current cleared Indication for Use for the B7-2C Balloon Catheter is as follows (the 510(k) was submitted with 2 model #'s with identical indications):

> *Olympus B5-2C/**B7-2C Balloon Catheters** are to be used for selective endoscopic bronchography, medicine injection to bronchi, saline injection*

associated with bronchoalveolar lavage, foreign body removal from bronchi and bronchial hemostasis.

The device design and materials are completely unchanged, it will be provided packaged and sterilized to ORA, and we will private label it. The only difference will be the package labeling and Instructions for Use indicating that the device is the **B7-2C Occlusion Balloon**, and the *modified Indication for Use*.

In the modified indication for use, the **B7-2C Occlusion Balloon** will also be available for localizing air leaks.

We proposed the following modified indication:

The B7-2C Occlusion Balloons is to be used for selective endoscopic bronchography, saline injection associated with bronchoalveolar lavage, bronchial hemostasis and airway occlusion to localize air leaks.

The proposed modified Indication for Use removes *medicine injection to bronchi, foreign body removal from bronchi* and adds *airway occlusion to localize air leaks*.

Both the predicate and proposed device, which is identical, are an accessory to Olympus bronchoscopes. Spiration will be private labeling the device with a modified name and Indications for use, which fall within the current Intended Use.

The device is introduced through the instrument channel of the bronchoscope. The device is constructed of the inflatable balloon, catheter, bifurcation, irrigation port, air feed cap and stopcock. The B7-2C device is 1050 mm in working length, with a pre-inflation diameter of 2.55 mm and a post-inflation diameter of 13 mm, with a max volume of 1.7 cc.

Device Materials (Patient Contacting)

The B7-2C Occlusion Balloon is manufactured with materials commonly used in medical device applications. The patient contacting materials are included in **Table 5-1** below:

Table 5-1 B7-2C Patient Contacting Materials

Patient Contacting Materials
Latex rubber
Polyethylene impregnated with barium sulfate

Biocompatibility testing was repeated on the subject device to support this 510(k) submission, to confirm that it meets current biocompatibility requirements.

How Provided

The B7-2C Occlusion Balloon is provided sterile and is disposable, intended for single patient use.

Proposed Indication for Use

The B7-2C Occlusion Balloon is to be used for selective endoscopic bronchography, saline injection associated with bronchoalveolar lavage, bronchial hemostasis and airway occlusion to localize air leaks.

Comparison to Predicate

A comparison table, **Table 5-2**, is included below, which illustrates the equivalence of the subject B7-2C device to the predicate device.

Table 5-2: Comparison of Key Characteristics of Proposed Device to Predicate Device

Device Name→ **Device Characteristics ↓**	**B7-2C Balloon Catheter (K962901)**	**B7-2C Occlusion Balloon (Proposed Device)**
Classification	II	II
Code of Federal Regulations	878.4680	878.4680
Prescription	Yes	Yes
Indication for Use	*Olympus B5-2C/B7-2C Balloon Catheters are to be used for selective endoscopic bronchography, medicine injection to bronchi, saline injection associated with bronchoalveolar lavage, foreign body removal from bronchi and bronchial hemostasis.*	*The Olympus B7-2C Occlusion Balloon is to be used for selective endoscopic bronchography, ~~medicine injection to bronchi~~, saline injection associated with bronchoalveolar lavage, ~~foreign body removal from bronchi,~~ bronchial hemostasis and airway occlusion to localize air leaks.*
Materials	• Latex rubber • Polyethylene impregnated with barium sulfate	Identical
Minimum Endoscope Channel Size	2.8 mm	Identical
Diameter	7 French	Identical
Length	1050 mm	Identical
Sterilization	Ethylene Oxide, Single Use	Identical

The intended use of the subject device is virtually identical to that of the predicate device with respect to bronchial hemostasis. Whereas the predicate device uses pressure against the airway walls to support hemostasis, the proposed device uses pressure against the airway to localize air leaks within the lung.

Performance Data

Performance testing has been completed on both the predicate device as well as the subject device, which is identical to the subject device. The B7-2C Occlusion Balloon was subjected to the following verification and validation tests, as applicable:

Biocompatibility

Repeat biocompatibility testing was conducted on the subject device to confirm that it meets current biocompatibility requirements. The tests included cytotoxity, intracutaneous irritation, materials mediated pyrogen, sensitization and systemic toxicity. All tests were successfully passed.

Sterilization/Shelf-Life

The device was validated to achieve a sterility assurance level of 10^{-6}.

Performance Testing

Testing was completed for the subject device to evaluate the ability of the B7-2C to successfully occlude airways. All tests (N=30) showed complete occlusion of the airway. Based on the statistical plan, this shows that the B7-2C balloon is capable of occluding airways at 90% conformance and 95% confidence. All acceptance criteria defined in the protocol was met.

Verification and burst testing bench was completed on the predicate device to confirm that the performance of the device conforms to mechanical and functional specifications. The testing included:

- Verification
- Burst testing

Conclusion (Statement of Equivalence)

As confirmed in the prior 510(k) for the predicate device, which is identical to the subject device, the device successfully passed all performance testing. For the subject device, biocompatibility testing was successfully passed, as well as bench testing to verify the ability of the device to successfully occlude airways.

As stated above, the intended use of the subject device is virtually identical to that of the predicate device with respect to bronchial hemostasis. Whereas the predicate device uses pressure against the airway walls to support hemostasis, the proposed device uses pressure against the airway to allow the physician to localize air leaks within the lung.

Since the modified device name and Indication for Use are the only changes, and the proposed Indication for Use is within the original Intended Use, we believe that the information provided supports a determination of substantial equivalence to the predicate device, and market clearance of the B7-2C Occlusion Balloon.