June 13, 2019

ADN International LLC
% Eric Bannon
Regulatory Consultant
AlvaMed, Inc.
935 Great Plain Avenue, #166
Needham, MA 02492

Re: K182159
Trade/Device Name: Strome-Blitzer Cytology Balloon
Regulation Number: 21 CFR§ 874.4710
Regulation Name: Esophagoscope (Flexible or Rigid) and Accessories
Regulatory Class: II
Product Code: EOX, FDX, BTR
Dated: May 15, 2019
Received: May 16, 2019

Dear Eric Bannon:

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,

Shanil P. Haugen, Ph.D.
Acting Assistant Division Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant 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)*
K182159

Device Name
Strome-Blitzer Cytology Balloon

Indications for Use *(Describe)*
The Strome-Blitzer Cytology Balloon device is indicated for use in the 4-quadrant collection and retrieval of surface cells from the esophagus in adults (22 years of age or older). The device may be delivered transorally under direct endoscopic visualization.

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.

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5.0 510(K) SUMMARY FOR STROME-BLITZER CYTOLOGY BALLOON CATHETER DEVICE

Date of Preparation:	August 6, 2018
Applicant (Submitter):	ADN International LLC 425 West 59th Street New York, NY 10019 Tel: (917) 703-2517
Correspondent Contact Information:	Eric Bannon AlvaMed Inc. 1116 Great Plain Avenue, #1 Needham, MA 02492 Tel: (888) 331-3485 Fax: (617) 249-0955 e-mail: ebannon@alvamed.com
Device Proprietary Name:	Strome-Blitzer Cytology Balloon
Device Common Name:	Cytology Balloon
Device Classification Regulation & Name:	21 CFR 874.4710, Esophagoscope (flexible or rigid) and accessories
Device Classification & Product Code:	Class II, EOX, FDX, BTR
Prior FDA Document Numbers:	None
Basis of Submission:	Traditional 510(k) based on K911588 (predicate device), K103437 (reference device)
Number of Devices in Submission:	1

5.1 Indications for Use

The Strome-Blitzer Cytology Balloon device is indicated for use in the 4-quadrant collection and retrieval of surface cells from the esophagus in adults (22 years of age or older). The device may be delivered transorally under direct endoscopic visualization.

5.2 Device Description

The Strome-Blitzer Cytology Balloon is an inflatable biopsy platform. It consists of a catheter with a silicone balloon at its distal end. The balloon has 6 collection pleats on its surface. Inside each pleat are 2 cytology collection strips for specimen collection. While the balloon is uninflated, the strips are covered by the balloon pleats. When inflated, the strips are exposed. The balloon inflates and deflates with the use of a syringe and attached catheter, and is a sterile, single-use device. There are 4 location indicator dots on the proximal balloon surface for orientation during esophagoscopy.

5.3 Substantial Equivalence Information

	Subject: Strome-Blitzer Cytology Balloon	**Predicate Device: Brandt Esophageal Cytology Balloon**	**Reference Device: US Endoscopy Cytology Brush**
Manufacturer	ADN International LLC	Wilson-Cook Medical, Inc.	United States Endoscopy Group, Inc.
510(k) Number	(to be determined)	K911588	K103437
Product Code	EOX, FDX, BTR	EOX	FDX
Regulation Number	874.4710	874.4710	876.1500
Regulation Description	Esophagoscope (flexible or rigid) and accessories	Esophagoscope (flexible or rigid) and accessories	Endoscope and accessories
Common Name	Cytology balloon	Cytology balloon	Endoscopic cytology brush

	Subject: Strome-Blitzer Cytology Balloon	**Predicate Device: Brandt Esophageal Cytology Balloon**	**Reference Device: US Endoscopy Cytology Brush**
Indications for Use	The Strome-Blitzer Cytology Balloon device is indicated for use in the 4-quadrant collection and retrieval of surface cells from the esophagus in adults (22 years of age or older). The device may be delivered transorally under direct endoscopic visualization.	The Brandt Esophageal Cytology Balloon is indicated for use in the collection and retrieval of surface cells in the esophagus.	The disposable Cytology Brush is intended to be used to retrieve cytological cell samples in the gastrointestinal tract.
Sterility	EO Sterilization	Data Not Available	EO sterilization
Single-Use	Yes	Yes	Yes
Biocompat-ibility	Complies with ISO 10993-1	Since 510(k) cleared, it is assumed that the device is biocompatible	Since 510(k) cleared, it is assumed that the device is biocompatible
Design Characteristics	• Balloon with pleats that open upon inflation to expose cytology collection strips • Device can be delivered transorally (under direct esophagoscopic visualization)	• Balloon with nipple-like projections for cytology collection • Passed alongside scope: transoral delivery (under direct esophagoscopic visualization) • Cytology results were similar between balloon and cytology brush	• Brush with abrasive bristles for cytology collection • Passes through scope working channel to desired location and is rotated to collect cells

	Subject: Strome-Blitzer Cytology Balloon	**Predicate Device: Brandt Esophageal Cytology Balloon**	**Reference Device: US Endoscopy Cytology Brush**
Dimensions	• Uninflated balloon outer diameter: 7 mm (without application of negative pressure) • Inflated balloon minimum outer diameter: 20 mm • Balloon length (without catheter): 84 mm • Minimum total working length: 1250 mm	• Uninflated balloon diameter: 10 mm • Inflated balloon outer diameter: 35 mm • Balloon length: 25 mm	• Brush diameter: 1-3 mm (various adult sizes) • Brush length: 1200-2400 mm (various adult sizes)

5.4 Comparison to Predicate Device

Both devices are designed for collection of esophageal tissue for cytology analysis. Both devices share similar designs, modes of operation, single-use disposition and sterility, intended use, and materials.

The primary differences between the predicate and subject devices are in their methods of sample collection and routes of delivery. The Strome-Blitzer Cytology Balloon uses cytology collection strips in pleats on the balloon surface rather than the nipple-like projections used in the predicate Brandt Balloon. The U.S. Endoscopy Cytology Brush (K103437) device was used in testing of the subject device in animals due to the unavailability of the Brandt Balloon and for its similarity to the cytology collection strips used in the subject device.

Finally, as demonstrated in the results of design verification, bench testing, and animal studies, any differences in design do not adversely affect performance compared to the predicate device, and the devices are substantially equivalent.

5.5 Summary of Supporting Data

ADN International LLC conducted the following performance testing for the Strome-Blitzer Cytology Balloon device.

5.5.1 Dimensional and Functional Performance Testing (Bench)

- Cytology collection strip inspection
- Balloon bond joint inspection
- Distal atraumatic tip inspection

- Device trackability and balloon to shaft joint integrity test
- Device total length
- Balloon length
- Catheter shaft internal diameter
- Catheter shaft outer diameter
- Maximum balloon profile (deflated)
- Axial orientation indicator dot inspection
- Balloon inflation-deflation cycle test
- Device kink resistance to evaluate balloon's ability to contain strips during device insertion and removal
- Balloon pressure evaluation and burst test
- Shaft to Luer joint tensile strength
- Shaft to balloon joint tensile strength

5.5.2 Animal Study of Safety and Effectiveness

The subject device was compared to the U.S. Endoscopy Cytology Brush due to commercial unavailability of the Brandt Balloon and similarity of cytology collection strips on the subject device to the action of the Cytology Brush.

Six swine underwent transoral esophagoscopy and cytology collection with the Strome-Blitzer Cytology Balloon and the U.S. Endoscopy Cytology Brush. There were no procedure-related complications in this study. Acceptance criteria for the subject device were met: cytologic examination of esophageal smears prepared with the Strome-Blitzer Cytology Balloon resulted in diagnostically useful cytology samples of high cellularity that were morphologically comparable to those generated with the reference cytology brush. Cytology collection procedures were well tolerated by the animals, with no inflammatory response or edema in the tissue of the distal esophagus in control or test areas.

5.6 Conclusion

A comparison of the Strome-Blitzer Cytology Balloon to the legally marketed predicate demonstrates the same intended use. Bench and animal testing support the conclusion that any differences in product design between subject and predicate do not raise new questions of safety and effectiveness for the proposed indication. Comparative testing demonstrates the subject device meets or exceeds established specifications. The device performs as well as or better than the legally marketed predicate, supporting substantial equivalence.