February 16, 2022

Axess Vision Technology
Marie-Hélène Bacheley
Regulatory Affairs and Quality Assurance Manager
Zone de la Liodière 6, rue de la Flottière
Joué-lès-Tours, Indre-et-Loire 37300
France

Re: K212886
Trade/Device Name: Broncoflex Agile, Broncoflex Vortex, Screeni
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: October 29, 2021
Received: November 4, 2021

Dear Marie-Hélène Bacheley:

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,

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT 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)*
K212886

Device Name
Broncoflex® Agile, Broncoflex® Vortex and Screeni®

Indications for Use *(Describe)*

Broncoflex® Agile and Broncoflex® Vortex

This video-bronchoscope is intended to provide an optical display of the pulmonary tract using a monitor (Screeni®) and to be used with endotherapy accessories and instruments.

This video-bronchoscope is designed for use exclusively in a hospital environment.

Endotherapy accessories and instruments
The effective length of an endoscopic instrument should be at least 30 cm greater than the effective length of the endoscope.

Model	Minimum compatible endotracheal tube size	Minimum compatible dual lumen endo-bronchial tube size	Maximum size of endotherapy instruments
Broncoflex Agile	≥ 5.0 mm	≥ 35 Fr.	≤ 1.2 mm
Broncoflex Vortex	≥ 6.0 mm	≥ 41 Fr.	≤ 2.6 mm

Patient Population
The Broncoflex can only be used on adult patients.

Screeni®

This device is designed for use exclusively in a hospital environment, in combination with an Axess Vision Broncoflex® video-bronchoscope.

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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510(k) Summary

Broncoflex® Vortex, Broncoflex® Agile and Screeni® (Flexible Bronchoscope System)

K212886

1. Submitter:

Submitter's Name: Axess Vision Technology
Address: Zone de la Liodière
6 rue de la flottière
37300 Joué-lès-Tours
France

Contact Person: Marie-Hélène BACHELEY
Regulatory Affairs & Quality Assurance Manager
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6 rue de la flottière
37300 Joué-lès-Tours
Phone Number: +33 (0)2 47 34 32 96
Fax Number: NA

Date Summary Prepared: 20 August 2021

2. Device:

Name of Device: Broncoflex® Agile; Product Reference: 20030001
Broncoflex® Vortex; Product Reference: 10030001
Screeni®; Product Reference: 30030001
Common or Usual Name: Flexible Bronchoscope
Classification Name: Bronchoscope (Flexible or Rigid) and accessories
Regulation Number: 21 CFR 874.4680
Device Class: II
Product Code: EOQ
Device Panel: Ear Nose & Throat

3. Predicate Devices:

Broncoflex® Agile, Broncoflex® Vortex and Screeni® (Broncoflex® Agile or Vortex + Screeni® = the system) are substantially equivalent to the legally marketed predicate devices:

Manufacturer: Axess Vision Technology
Trade Name: Broncoflex® Agile
Broncoflex® Vortex
Screeni®
510(K) Number: K202180

This predicate has not been subject to a design-related recall.

4. Device Description:

Broncoflex Agile and Broncoflex Vortex are a single-use video-bronchoscope which is part of a system made up of the endoscope (Broncoflex) and its reusable display monitor (Screeni). The video-bronchoscope is intended to provide an optical display of the pulmonary tract using a monitor (Screeni) and to be used with endotherapy accessories and instruments. The applied part of the medical device is the whole of the flexible tubing containing the insertion tube, the articulated section and the distal tip (BF type applied part: BF). Broncoflex is sterile and supplied ready to use in its sealed packaging (sterilization method ethylene oxide). The Screeni is a reusable nonsterile medical device and is a video processor with integrated touch interface designed to display live imaging data captured by Broncoflex Agile and Broncoflex Vortex. The consumables (Broncoflex) are supplied in sets of 5 in a carton. Inside this box, each sterilized consumable is placed in a single sterile pouch. Screeni is supplied in a carton with all the accessories (quick mounting bracket, knurled screw, power supply, EU/US/UK/AU adaptors and video cable (HDMI/DVI)). Broncoflex Agile and Broncoflex Vortex are the same devices except for some dimensional aspects such as external diameter of insertion tube, distal tip outer diameter and working channel inner diameter. Indeed, Broncoflex Agile has an applied part with a smaller diameter than the Broncoflex Vortex.

5. Indications for Use:

1. Broncoflex Agile and Vortex

This video-bronchoscope is intended to prove an optical display of pulmonary tract using a monitor (Screeni®) and to be used with endotherapy accessories and instruments.

This video-bronchoscope is designed for use exclusively in a hospital environment.

Endotherapy accessories and instruments
The effective length of an endoscopic instrument should be at least 30 cm greater than the effective length of the endoscope.

Model	Minimum compatible endotracheal tube size	Minimum compatible dual lumen endo-bronchial tube size	Maximum size of endotherapy instruments
Broncoflex Agile	≥ 5.0 mm	≥ 35 Fr.	≤ 1.2 mm
Broncoflex Vortex	≥ 6.0 mm	≥ 41 Fr.	≤ 2.6 mm

Patient Population
The Broncoflex can only be used on adult patients.

2. Screeni

This device is designed for use exclusively in a hospital environment, in combination with an Axess Vision Broncoflex® video-bronchoscope.

6. Comparison of technological characteristics with the predicate device:

1. Broncoflex Agile and Vortex

Broncoflex Agile and Broncoflex Vortex are technologically substantially equivalent to the predicate devices. The subject devices do not raise any new issues of safety or effectiveness based on the similarities to the predicate devices.

Table 1: Broncoflex Subject and Predicate devicesTechnical Characteristics

Type	Broncoflex® Vortex Subject device	Broncoflex® Agile Subject device	Broncoflex® Vortex Predicate device	Broncoflex® Agile Predicate device
Product reference	10030001	20030001	10030001	20030001
Field of vision direction	0°	0°	0°	0°
Field angle	87,5°	87,5°	87,5°	87,5°
Field depth	5 - 50 mm	5 - 50 mm	5 - 50 mm	5 - 50 mm
High/low deflection angle	200°/200°	220°/220°	200°/200°	220°/220°
External diameter of insertion tube	5.4 mm	3.6 mm	5.4 mm	3.6 mm
Distal end outer diameter	5.6 mm	3.9 mm	5.6 mm	3.9 mm
Operator channel inner diameter	2.8 mm	1.4 mm	2.8 mm	1.4 mm
Working length	605 mm	605 mm	605 mm	605 mm
Lighting system	2 LEDs	2 LEDs	2 LEDs	2 LEDs
Image resolution	400x400	400x400	400x400	400x400
Sterilisation	Ethylene oxide	Ethylene oxide	Ethylene oxide	Ethylene oxide

The Broncoflex Vortex and Broncoflex Agile are the same as the predicate devices in the following areas:

- Bronchoscope – used to reach the target organs, tissues and subsystems (pulmonary tract)
- Device inserted through oral or nasal route
- Viewing of the upper airways and of the bronchial tree
- Performance of other procedures such as as performing examinations requiring suction of secretions or the use of endotherapy accessories or instruments designed for use in combination with a bronchoscope
- Single-use devices provided sterile
- Field of vision direction
- Lighting system (2 LEDs)
- Image resolution
- Sterile with ETO

2. Screeni

Screeni is technologically substantially equivalent to the predicate device.

Table 2: Screeni and aViewTechnical Characteristics

Type	Screeni® Subject device	Screeni® Predicate device
Product reference	**30030001**	**30030001**
ELECTRICAL CHARACTERISTICS		
Power requirement	100-240V AC / 50-60Hz / 0.6A	100 - 240V AC; 50-60Hz; 0.6A
Power output	15 VDC / 2A	18V DC; 1.67A
Type of protection against electrocution	Class 2	Class 2
Battery type	Lithium-Ion battery (11,25V - 2950mAh or 10,8V – 3350mAh)	Lithium-Ion battery (11,25V - 2950mAh or 10,8V – 3350mAh)
Battery Operation	At least 3 hours (for a new and fully charged battery)	At least 3 hours (for a new and fully charged battery)
MECHANICAL CHARACTERISTICS		
Dimensions	L: 300 mm x H: 200 mm x D: 110 mm (mounting bracket folded)	L: 300 mm x H: 200 mm x D: 110 mm (mounting bracket folded)
Weight	1.8 kg (with mounting bracket)	1.8 kg (with mounting bracket)
Mounting interface	VESA 75 mm	VESA 75 mm

TOUCH SCREEN		
Resolution	1280x800	800x480
Display type	10.1-inch TFT LCD	10.1-inch TFT LCD
MISCELLANEOUS CHARACTERISTICS		
IP ProtectionClassification System	IP30	IP30
Exported file formats	Photos: .JPG Videos: .AVI (h264 compression)	Photos: .JPG Videos: .AVI (h264 compression)
TECHNICAL CHARACTERISTICS		
Internal storage capacity	16 Gb (can store up to 14 h of video or more than 100,000 photos)	16 Gb (can store up to 14 h of video or more than 100,000 photos)
Connections	Type A (for USB key connection only)	Type A (for USB key connection only)
	Endoscope port	Endoscope port
	DC 15V / 2A input	DC 15V / 2A input
	HDMI port: video output to be used with a DVI compatible monitor only and with the HDMI/DVI cable supplied.	NA

The Screeni is the same as the predicate device in the following areas:

- Viewing of the upper airways and of the bronchial tree
- Correct image orientation
- Touch screen
- Battery time/operation (3 hours)
- Battery type (Lithium-ion)
- Storage capacity
- USB, endoscope and power out (electrical power) connection

The Screeni is different from the predicate device in the following area:

- HDMI port for use with a DVI compatible monitor and the provided HDMI/DVI cable to duplicate the live image from the endoscope to a secondary monitor

⇨ This difference has no impact on performance, safety nor effectiveness of the devices.

7. Non-Clinical Performance data:

As part of demonstrating safety and effectiveness of Flexible Bronchoscope System (= Broncoflex® Agile or Broncoflex® Vortex + Screeni®) and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Axess Vision Technology completed a number of non-clinical performance tests. The Flexible Bronchoscope System meets all the requirements for overall design, sterilization, biocompatibility, sterile packaging integrity, shelf life, transportation, electromagnetic compatibility and electrical safety results confirming that the design output meets the design inputs and specifications for the device.

The Flexible Bronchoscope System passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Electrical safety testing per IEC 60601-1:2012 and IEC 60601-2-18:2009
- Electromagnetic Compatibility (EMC) testing per IEC 60601-1-2:2014 / A1:2020 (Ed. 4.1)
- Software verification and validation testing per IEC 62304:2006/A1 & FDA Guidance

8. Conclusion:

Based on the indications for use, principle of operation, overall technological characteristics and the performance data provided, it is concluded that the functionality and the intended use of the Broncoflex® and Screeni® system is equivalent to the cited predicate devices (= Broncoflex® and Screeni® devices), and is therefore determined to be substantially equivalent.