May 11, 2023

GA Health Company Limited
Rainy Lam
Assistant Regulatory Affairs Manager
2 On Yiu Street
Unit 18, 21/F, Metropole Square
Shatin
Hong Kong

Re: K230280
Trade/Device Name: ANDORATE® Suction Valve and ANDORATE® Biopsy Valve
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and Accessories
Regulatory Class: Class II
Product Code: KTI
Dated: February 1, 2023
Received: April 12, 2023

Dear Rainy Lam:

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,

Joyce C. Lin -S

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)*
K230280

Device Name
ANDORATE® Suction Valve
ANDORATE® Biopsy Valve

Indications for Use *(Describe)*
The single use ANDORATE® Suction Valve is used to control the suction function of an endoscope during the endoscopic procedure.

The single use ANDORATE® Biopsy Valve is used to cover the opening to the biopsy/suction channel of endoscope. The biopsy valve provides access for endoscopic device passage and exchange and minimizes leakage of biomaterial from the biopsy port through the endoscopic procedure.

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

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

1. Submission Sponsor

Submitter's Name:	GA Health Company Limited
Submitter's Address:	Unit 18, 21/F, Metropole Square 2 On Yiu Street, Shatin, N.T, Hong Kong, CHINA
Establishment Registration No.:	3014749926

2. Sponsor Contact

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3. Date Prepared

9 May 2023

4. Device Identification

Device Name:	ANDORATE® Suction Valve
Common Name:	Suction valve
Classification Number:	21 CFR 874.4680
Classification Name:	Bronchoscope (flexible or rigid) and accessories
Product Code:	KTI
Product Code Name:	Bronchoscope Accessory
Regulation Class:	2
Device Panel:	Ear Nose & Throat

Device Name:	ANDORATE® Biopsy Valve
Common Name:	Biopsy valve
Classification Number:	21 CFR 874.4680
Classification Name:	Bronchoscope (flexible or rigid) and accessories
Product Code:	KTI
Product Code Name:	Bronchoscope Accessory
Regulation Class:	2
Device Panel:	Ear Nose & Throat

5. Predicate Device Identification

Predicate Device 510(k) No.:	K061313
Predicate Device Trade Name:	EVIS EXERA II 180 System

Predicate Device Product Code: EOQ – Bronchoscope (Flexible Or Rigid)

6. Device Description:

The subject devices are intended for single-use and are supplied sterile. Table 1 shows the components included in the submission.

Table 1 – Components included in the Submission

Components	Qty	Product Code	Regulation Number	Regulatory Classification
ANDORATE® Suction Valve	1	KTI – Bronchoscope Accessory	21 CFR 874.4680	2
ANDORATE® Biopsy Valve	1	KTI – Bronchoscope Accessory	21 CFR 874.4680	2

The suction valve is designed to be attached to the suction port of the bronchoscope and the biopsy valve is designed to be attached to the biopsy port of the bronchoscope. The activation of the suction valve allows the user to aspirate excess fluids or other debris obscuring the bronchoscopic image while biopsy valve provides access for endoscopic device passage and exchange, helps maintain insufflation and minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure. The suction valve and biopsy valve kit is compatible with Olympus® 160/180/190/260/290 Series Bronchoscopes.

7. Indications for Use:

The single use ANDORATE® Suction Valve is used to control the suction function of an endoscope during the endoscopic procedure.

The single use ANDORATE® Biopsy Valve is used to cover the opening to the biopsy/suction channel of endoscope. The biopsy valve provides access for endoscopic device passage and exchange and minimizes leakage of biomaterial from the biopsy port through the endoscopic procedure.

8. Technological Characteristics

Table 2 summarizes the suction valve and biopsy valve technological characteristics as compared to the predicate device.

Table 2 Summary of design, features and principles of operation and technological characteristics between the subject device and predicate device

Specification	**Predicate Device**	**Subject Device**	**Substantial Equivalence**
Product code	EOQ	KTI	Substantial Equivalent
Regulatory Classification	2	2	Identical
Regulation No	21 CFR 874.4680	21 CFR 874.4680	Identical
Regulation Description	Bronchoscope (Flexible Or Rigid)	Bronchoscope Accessory	Identical

Specification	Predicate Device	Subject Device	Substantial Equivalence
Indications for Use	The suction valve is depressed to activate suction. The valve is also used to remove any fluid or debris adhering to the objective lens. The biopsy valve is attached to the instrument channel port, and an EndoTherapy accessory can be inserted or a syringe can be attached.	The single use ANDORATE® Suction Valve is used to control the suction function of an endoscope during the endoscopic procedure. The single use ANDORATE® Biopsy Valve is used to cover the opening to the biopsy/suction channel of endoscope. The biopsy valve provides access for endoscopic device passage and exchange and minimizes leakage of biomaterial from the biopsy port through the endoscopic procedure.	Substantial Equivalent
Compatibility	Olympus® 180 Series Bronchoscopes	Olympus® 160/180/190/260/290 Series Bronchoscopes	Substantial Equivalent
Environment of Use	Hospital and or clinics	Hospital and or clinics	Identical
Single Use or Reusable	Single Use	Single Use	Identical
Material	Silicone, Polypropylene, Polyethylene	Polyvinyl Chloride, Acrylonitrile Butadiene Styrene, Silicone Rubber	Substantial Equivalent
Manufacturing method	Injection molding	Injection molding	Identical
Packaging	Packaged in a sealed pouch	Packaged in a sealed pouch	Substantial Equivalent
Sterilization	Yes	Yes	Substantial Equivalent
Shelf Life	3 years	3 years	Substantial Equivalent

9. Performance Test

The bench testing was performed to support substantial equivalence on both the subject device and the predicate device. The following bench testing was performed – endoscope compatibility test, suction flow, vacuum leak, water leak test, pressing force test and fatigue test for suction valve and endoscope compatibility, vacuum leak and squeegee leak test for biopsy valve. The performance data demonstrated that the subject devices met established specifications.

10. Sterilisation

All the subject devices are sold in a sterile package. The subject devices have been sterilized in a validated EO sterilization cycle. The EO sterilization cycle has a Sterility Assurance Level (SAL) of 10^{-6}. EO residuals on the components are below the maximum levels defined in

ANSI/AAMI/ISO 10993-7 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide sterilization residuals.

11. Shelf Life

The subject devices have a three (3) years shelf life, based on the design and existing sterile barrier data from the existing packaging. Packaging integrity test in accordance with ASTM F88/F 88M-15, 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 D 3078-02, Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission, DIN 58953-6, Sterilization – Sterile Supply – Part 6: Microbial Barrier Testing of Packaging Materials for Medical Devices Which Are to be Sterilized and ISO11737-2, Sterilization of Medical Devices – Microbiological Methods – Part 2: Tests of Sterility Performed in the Definition, Validation and Maintenance of a Sterilization Process and performance test were conducted after accelerated aging test according to ASTM F 1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. The test result can imply that the subject devices can provide and maintain a sterile barrier and its intended performance for at least the claimed shelf life.

12. Biocompatibility

The biocompatibility of the subject device was conducted in accordance with the FDA guideline “Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”. Biocompatibility testing is conducted on subject device in accordance with the ISO 10993 standard. The suction valve is non-patient contacting device while the biopsy valve is classified as an indirect patient contacting device and surface device with mucosal membrane contact for a limited duration (not more than 24 hours). The biocompatibility test was performed in accordance with the following standards – ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity and ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. Test results show that the subject device is biocompatible.

13. Conclusion

The subject devices have the same intended use as the predicate device. Based on comparison of technological characteristics and evaluation of the characteristics through performance testing, the subject devices do not raise different questions of safety and effectiveness compared to the predicate. From a clinical perspective and comparing design specifications, the subject devices and the predicate device are substantially equivalent.