June 24, 2020

GA Health Company Limited
% Rafael Aguila
Responsible Third-Party Official
Accelerated Device Approval Services, LLC
6800 S.W. 40th Street, Ste. 444
Ludlum, FL 33155-3708

Re: K200495
Trade/Device Name: Andorate Disposable Air/Water Valve
Andorate Disposable Suction Valve
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODC
Dated: February 27, 2020
Received: February 28, 2020

Dear Rafael Aguila:

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.
Assistant 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)*
K200495

Device Name

Andorate Disposable Air/Water Valve, Andorate Disposable Suction Valve

Indications for Use *(Describe)*

The Andorate® Disposable Suction Valve is used to control the suction function of an endoscope (Fujifilm 700 series) during a GI Endoscopic procedure.

The Andorate® Disposable Air/Water valve is used to control the air/water function of an endoscope (Fujifilm 700 series) during a GI 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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

Contact Person:	Cindy Ye Chief Executive Officer
Telephone:	+852 2833 9010
Email:	cindy@andorate.com

3. Date Prepared

June 23rd 2020

4. Device Identification

Trade Device Name:	Andorate® Disposable Suction Valve
Common Device Name:	Suction valve for endoscope
Product Code:	ODC – Endoscope Channel Accessory
Regulation Number:	876.1500
Classification:	2
Regulation Name:	Endoscope and Accessories

Trade Device Name:	Andorate® Disposable Air/Water Valve
Common Device Name:	Air/water valve for endoscope
Product Code:	ODC – Endoscope Channel Accessory
Regulation Number:	876.1500
Classification:	2
Regulation Name:	Endoscope and Accessories

5. Predicate Device Identification

Predicate Device 510(k) No.:	K172916
Predicate Device Trade Name:	FUJIFILM Endoscope
Predicate Device Product Code:	ODC

6. Device Description:

The subject devices are intended for single-use and are supplied sterile. Disposable suction and air/water help preventing potential safety risks and eliminate the need for manual cleaning and reprocessing. The subject devices are easily incorporated into infection prevention policies as a single use item. Table 1 shows the components included in the application.

Table 1 – Components included in the application

Components	Qty	Classification Name	Regulation Number	Classification
Andorate® Disposable Suction Valve	1	ODC – Endoscope Channel Accessory	876.1500	2
Andorate® Disposable Air/Water Valve	1	ODC – Endoscope Channel Accessory	876.1500	2

The suction valve is designed to be attached to the suction port of the endoscope and the air/water valve is designed to be attached to the air/water port of the endoscope. The activation of the suction valve allows the user to aspirate excess fluids or other debris obscuring the endoscopic image, while the activation of the air/water valve allows the user to control air and water flow to assist in cleansing the lens during procedures.

The suction and air/water are housed together with biopsy valve and auxiliary water connector in a single tray and packaged in sealed packed. The subject devices are supplied as sterile The subject devices in this submission have the same operation and method of action with the predicate device.

According to the Medical Device Recalls database in FDA website, no product recall was found for the predicate device. According to the FDA MAUDE database, safety issues on fluid leakage and backflow were identified. In the performance test, the leakage test and backflow test were conducted for verification.

There were no prior submissions for the subject devices.

7. Intended Use: The Andorate® Disposable Suction Valve is used to control the suction function of an endoscope (Fujifilm 700 series) during a GI Endoscopic procedure.

8. Intended Use: The Andorate® Disposable Air/Water valve is used to control the air/ water function of an endoscope (Fujifilm 700 series) during a GI Endoscopic procedure.

9. Technological Characteristics

The following table (Table 2) is summaries of the Andorate® Disposable Suction Valve and Andorate® Disposable Air/Water 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 and predicate devices (suction and air/water valves).

Specification	**Predicate Device**	**Subject Devices**	**Substantial Equivalence**
Device name	**FUJIFILM Endoscope (Suction and air/water valve)**	**Andorate® Disposable Suction Valve** and **Andorate® Disposable Air/Water Valve**	N/A
K number	K172916	K200495	N/A
Manufacturer	FUJIFILM Corporation	GA Health Company Limited	N/A

Product code	FDF, FDS	ODC	N/A
Classification	2	2	Identical
Regulation No	876.1500	876.1500	Identical
Regulation Name	Endoscope and accessories	Endoscope and accessories	Identical
Supplied Sterile	No*	Yes	Substantial Equivalent
Compatibility	FUJIFILM 700 series endoscope	FUJIFILM 700 series endoscope	Identical
Intended Use	The suction valve is a medical device that is attached to a FUJIFILM gastrointestinal endoscope in order to suck mucus or air in the body cavity. The air/water valve is a medical device that is attached to a FUJIFILM gastrointestinal endoscope in order to jet air or water.	The Andorate® Disposable Suction Valve is used to control the suction function of an endoscope (Fujifilm 700 series) during a GI Endoscopic procedure. The Andorate® Disposable Air/Water Valve is used to control the air/water function of an endoscope (Fujifilm 700 series) during a GI Endoscopic procedure.	Substantial Equivalent
Environment of Use	Hospital and or clinics	Hospital and or clinics	Identical
Single Use, Disposable	Yes	Yes	Identical
Material	Polycarbonate, stainless steel 304, thermoplastic elastomer	Acrylonitrile Butadiene Styrene, silicone, Stainless Steel 304	Substantial Equivalent
Packaging	Each model packed in a PE bag with a carton box	Suction, air/water, biopsy valves and auxiliary water connector are housed in a single tray and packaged in a sealed pouched	Substantial Equivalent
Manufacturing method	Injection moulding and over-moulding.	Injection moulding	Substantial Equivalent
Sterilization	Supplied non-sterile Sterilized after each use	EO gas	Identical
Shelf Life	1 year	1 year	N/A

*Remark: The predicate device is supplied as non-sterile and the end-user should be sterilized prior using, while the subject device is sold as sterile in which no sterilization is needed by the end-user prior to using.

10. Non-Clinical Performance Data

The bench testing was performed to support substantial equivalence. The following testing were performed on subject devices from initial production lots, including sterilization.

10.1 Performance Test

10.1.1 Andorate® Disposable Suction Valve

10.1.1.1 Assembling Integrity
10.1.1.2 Endoscope Compatibility
10.1.1.3 Depression Force
10.1.1.4 Vacuum Leak Test
10.1.1.5 Suction Flow Test

10.1.2 Andorate® Disposable Air/Water Valve

10.1.2.1 Endoscope Compatibility Testing
10.1.2.2 Air Leakage Testing
10.1.2.3 Assembling Integrity Verification
10.1.2.4 Air Flow Test
10.1.2.5 Depression Force Testing
10.1.2.6 Water Flow Test

10.2 Sterilization

All the subject devices are sold in sterile packaging. Also, 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 10993-7:2008 *Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide sterilization residuals.* The subject and the predicate devices, are not labeled as pyrogen-free because they do not have any blood or cerebrospinal fluid contact.

10.3 Shelf Life

The Andorate® Disposable Suction and Air/Water have a one (1) year expiration date. The subject devices are packaged in a paper/film pouch respectively. These pouches have been tested by Sanitation Environment Technology Institute, Soochow University. The tests conducted including accelerated aging, seal strength, dye penetration, microbial barrier properties, vacuum leak test and the sterility test. The performance test was conducted for the subject devices after the accelerated aging process. The test result can imply that the subject devices can provide and maintain a sterile barrier and its intended performance before the expiration date.

10.4 Biocompatibility

The biocompatibility of the subject devices were 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””. It included the following tests.

- Acute Systemic Toxicity Test
- In Vitro Cytotoxicity
- Skin sensitization
- Irritation

The subject devices are classified as surface devices with mucosal membrane contact for a limited duration (not more than 24 hours). The test result shows that the subject devices are biocompatible.

11. Clinical Testing

Similar devices have been on the market for many years with proven safety and efficacy for the use of the device. These devices have no direct patient contact. Based on this history and the use of the device, clinical testing was not necessary to support substantial equivalence data. The non-clinical testing performed supports safety and efficacy of the devices and provides data to show substantial equivalence to the predicate device.

12. Conclusion

The subject devices have the same intended use as the predicate device. Based on the technological characteristics and overall performance of the devices in bench testing, there are no significant differences exist between the subject devices and the predicate devices. The subject devices do not raise any new issues of safety and effectiveness. From a clinical perspective and comparing design specifications, the subject devices and the predicate device are substantially equivalent.