May 15, 2020

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

Re: K200479
Trade/Device Name: AquaPulse Auxiliary Water Connector
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCX
Dated: May 6, 2020
Received: May 7, 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)*

K200479

Device Name
AquaPulse® Auxiliary Water Connector

Indications for Use *(Describe)*
The AquaPulse® Auxiliary Water Connector is used in conjunction with irrigation tubing (not supplied), intended to provide irrigation via irrigation fluids such as sterile water supplied to the Fujifilm GI endoscopes during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump.

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.:	No number listed

2. Sponsor Contact

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

3. Date Prepared

15th Nov 2019

4. Device Identification

Trade Device Name:	AquaPulse® Auxiliary Water Connector
Common Device Name:	Connector between the tube and endoscope
Product Code:	OCX – Endoscopic Irrigation/Suction
Regulation Number: Regulatory	System 21 CFR 876.1500
Classification:	2

5. Predicate Device Identification

Predicate Device 510(k) No.:	K092429
Predicate Device Trade Name:	ENDOGATOR
Predicate Device Product Code:	FEQ

6. Device Description:

The subject device is intended for single-use and are supplied sterile. Table 1 shows the components included in the application.

Table 1 – Components included in the application

Components	Qty	Product Code	Regulation Number	Regulatory Classification
AquaPulse® Auxiliary Water Connector	1	OCX – Endoscopic Irrigation/Suction System	21 CFR 876.1500	2

The auxiliary water connector is manufactured for use in conjunction with irrigation tubing, and together with Fujifilm 500/600/700 series endoscope. It is designed to be attached to the

auxiliary water port of the endoscopes. The auxiliary water connector consists of a backflow valve which prevent the backflow of water or biomaterials from the endoscope to the sterile water bottle.

The auxiliary water connector is packed individually in a sealed packed. The subject device is supplied as sterile The subject device 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 AquaPulse® Auxiliary Water Connector is used in conjunction with irrigation tubing (not supplied), intended to provide irrigation via irrigation fluids such as sterile water supplied to the Fujifilm GI endoscopes during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump.

8. Technological Characteristics

The following table (Table 2) is summaries of the AquaPulse® Auxiliary Water Connector technological characteristics as compared to the predicate devices.

Table 2 Summary of design, features and principles of operation and technological characteristics between the subject and predicate devices (Auxiliary water connector)

Specification	Predicate Device	Subject Device	Substantial Equivalence
Device name	**ENDOGATOR (Irrigation Accessories auxiliary water connector)**	**AQUAPULSE® Auxiliary Water Connector**	N/A
K number	K092429	/	N/A
Manufacturer	Medivators, Inc.	GA Health Company Limited	N/A
Product code	FEQ	OCX	N/A
Regulatory Classification	2	2	Identical
Regulation No	21 CFR 876.1500	21 CFR 876.1500	Identical
Regulation Name	Endoscope and accessories	Endoscope and accessories	Identical
Supplied Sterile	Yes	Yes	Identical
Compatibility	Fujifilm GI endoscopes	Fujifilm GI endoscopes	Similar
Intended Use	The ENDOGATOR® system is intended to provide irrigation via sterile water during GI endoscopic	The AquaPulse® Auxiliary Water Connector is used in conjunction with irrigation tubing (not supplied),	Identical

	procedures when used in conjunction with an irrigation pump (or cautery unit).	intended to provide irrigation via irrigation fluids such as sterile water supplied to the Fujifilm GI endoscopes during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump.	
Environment of Use	Hospital and or clinics	Hospital and or clinics	Identical
Single Use, Disposable	Yes	Yes	Identical
Material	Polycarbonate, silicone	Polycarbonate, silicone	Substantial Equivalent
Packaging	It is packaged in a sealed pouch individually	It is packaged in a sealed pouch individually	Identical
Manufacturing method	Injection moulding	Injection moulding	Similar
Backflow Prevention Design	Diaphragm in the connector allow pressurized water passing through in one-way but not the other way	Diaphragm in the connector allow pressurized water passing through in one-way but not the other way	Identical
Sterilization	EO gas	EO gas	Identical
Shelf Life	Three years	One year	N/A

9. 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.

9.1 Performance Test

9.1.1 Compatibility with irrigation tubing
9.1.2 Compatibility with endoscope
9.1.3 Water Flow Test
9.1.4 Air Leakage Test
9.1.5 Water Leakage Test
9.1.6 Backflow Performance Test

9.2 Sterilization

All the subject device is sold in sterile package, like the Medivators predicate devices. 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.

9.3 Shelf Life

The AquaPulse® Auxiliary Water Connector have a one (1) year expiration date. The subject devices is 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.

9.4 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"". 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.

10. 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 devices.

11. Conclusion

The subject devices have the same intended use as the predicate devices. 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.