December 10, 2020

GA Health Company Limited
Cindy Ye
Chief Executive Officer
Unit 18, 21/F, Metropole Square, 2 On Yiu Street, Shatin
Hong Kong,
CHINA

Re: K202560
Trade/Device Name: AquaPulse® Irrigation Tubing
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCX
Dated: November 4, 2020
Received: November 9, 2020

Dear Cindy Ye:

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)*
K202560

Device Name
AquaPulse® Irrigation Tubing

Indications for Use *(Describe)*
The 24 hour use AquaPulse® Irrigation Tubing (tubing and accessories to accommodate various GI endoscopes and irrigation pumps) is intended to provide irrigation via a sterile water bottle 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.:	3014749926

2. Sponsor Contact

Cindy Ye
Chief Executive Officer
Telephone: +852 2833 9010
Email: cindy@gahealth.net

Lam Wing Yu
Senior Product Compliance Specialist
Telephone: +852 2833 9010
Email: rainy@gahealth.net

3. Date Prepared

10 Dec 2020

4. Device Identification

Trade Device Name:	AquaPulse® Irrigation Tubing
Common Name:	Irrigation tubing for endoscope
Product Code:	OCX
Produce Code Name:	Endoscopic Irrigation/Suction System
Regulation Number:	21 CFR 876.1500
Regulation Name:	Endoscope and accessories
Regulatory Classification:	2
Device Panel:	Gastroenterology/Urology

5. Predicate Device Identification

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

6. Device Description:

The AquaPulse® Irrigation Tubing is intended for 24-hour use and then discarded. The irrigation tubing is manufactured for use in conjunction with sterile water bottle, and together with irrigation pumps. The irrigation tubing is individually packed in sealed package, sold as a sterile device. The irrigation tubing is designed to be attached to the auxiliary water connector or biopsy irrigation accessory and to be inserted into pump head of the irrigation pump to provide irrigation through the auxiliary water channel to the distal end of endoscope.

7. Indications for Use:

The 24 hour use AquaPulse® Irrigation Tubing (tubing and accessories to accommodate various GI endoscopes and irrigation pumps) is intended to provide irrigation via a sterile water bottle during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump.

8. Technological Characteristics

Table 2 summarizes the irrigation tubing technological characteristics as compared to the predicate devices.

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

Specification	Predicate Device	Subject Device	Substantial Equivalence
Product code	FEQ	OCX	Identical
Regulatory Classification	2	2	Identical
Regulation No	21 CFR 876.1500	21 CFR 876.1500	Identical
Regulation Description	Endoscope and accessories	Endoscope and accessories	Identical
Compatibility	Olympus® AFU-100, Olympus® OFP, ERBE® EIP2 or EGP-100 Irrigation Pumps	Olympus® OFP, Endo Status™ EGA-500 and Endogator® EGP-100 Irrigation Pump	Substantial Equivalent
Indications for Use	The ENDOGATOR® system is intended to provide irrigation via sterile water during GI endoscopic procedures when used in conjunction with an irrigation pump (or cautery unit).	The 24 hour use AquaPulse® Irrigation Tubing (tubing and accessories to accommodate various GI endoscopes and irrigation pumps) is intended to provide irrigation via a sterile water bottle during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump.	Substantial Equivalent
Environment of Use	Hospital and or clinics	Hospital and or clinics	Identical
Single Use, Disposable	24-hour use then discard	24-hour use then discard	Identical
Material	Polycarbonate and Polyvinyl Chloride	Polycarbonate and Polyvinyl Chloride	Substantial Equivalent
Packaging	Irrigation tubing is packaged in a sealed pouch	Irrigation tubing is packaged in a sealed pouch	Identical
Manufacturing method	Injection molding and extrusion	Injection molding and extrusion	Identical

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	3 years	1 year	Substantial Equivalent

9. Performance Test

The bench testing was performed to support substantial equivalence such as verification tests on flow performances of subject devices and predicate devices. The performance data demonstrated that the subject devices met established specifications.

10. Sterilization

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 one (1) year shelf life, based on the design and existing sterile barrier data from the existing packaging. Packaging integrity test and performance test were conducted after accelerated aging test. 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 devices 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”. 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.

13. 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.