August 1, 2023

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

Re: K231602
Trade/Device Name: Protego Air Water Connector; Protego Air Water Bottle Tubing; Protego Hybrid Tubing
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCX
Dated: June 1, 2023
Received: June 1, 2023

Dear Wing Yu 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,

Shanil P. Haugen -S

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231602

Device Name

Protego Air Water Connector;
Protego Air Water Bottle Tubing;
Protego Hybrid Tubing

Indications for Use *(Describe)*

Protego Air Water Connector
The single use Protego Air Water Connector is intended to connect an air/CO2 source, a sterile water source and an endoscope to supply air/CO2 and water during gastrointestinal endoscopic procedures.

Protego Air Water Bottle Tubing
Protego Air Water Bottle Tubing is to connect an air/CO2 source, a sterile water source (water bottle), and an endoscope to supply air/CO2 and water during gastrointestinal endoscopic procedures. It is a 24-hour multi-patient use device.

Protego Hybrid Tubing
Protego Hybrid Tubing is intended to connect an air/CO2 source, a sterile water source and an endoscope to supply air/CO2, water and irrigation during endoscopic procedures in conjunction with an irrigation pump. It is a 24-hour multi-patient use device.

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

1 June 2023

4. Device Identification

Device Name:	Protego Air Water Connector
Common Name:	Air Water Connector
Classification Number:	21 CFR 876.1500
Classification Name:	Endoscope and accessories
Product Code:	OCX
Product Code Name:	Endoscopic Irrigation/Suction System
Regulation Class:	2
Device Panel:	Gastroenterology/Urology

Device Name:	Protego Air Water Bottle Tubing
Common Name:	Air Water Bottle Tubing
Classification Number:	21 CFR 876.1500
Classification Name:	Endoscope and accessories
Product Code:	OCX
Product Code Name:	Endoscopic Irrigation/Suction System
Regulation Class:	2
Device Panel:	Gastroenterology/Urology

Device Name:	Protego Hybrid Tubing
Common Name:	Hybrid Tubing
Classification Number:	21 CFR 876.1500

Classification Name:	Endoscope and accessories
Product Code:	OCX
Product Code Name:	Endoscopic Irrigation/Suction System
Regulation Class:	2
Device Panel:	Gastroenterology/Urology

5. Predicate Device Identification

Primary Predicate Device 510(k) No.:	K191366
Primary Predicate Device Trade Name:	Andorate Air Water Bottle Tubing
Primary Predicate Device Product Code:	OCX – Endoscopic Irrigation/Suction System
Secondary Predicate Device 510(k) No.:	K102855
Secondary Predicate Device Trade Name:	Universal Irrigation Solution Hybrid
Secondary Predicate Device Product Code:	OCX – Endoscopic Irrigation/Suction System

6. Device Description:

The Protego Air Water Connector is intended for single use then discarded. The Protego Air Water Bottle Tubing and Protego Hybrid Tubing are intended for 24-hour use then discarded. All Protego Air Water Connector, Protego Air Water Bottle Tubing and Protego Hybrid Tubing are provided sterile. Table 1 shows the components included in the submission.

Table 1 – Components included in this Submission

Components	Qty	Product Code	Regulation Number	Regulatory Classification
Protego Air Water Connector	1	OCX – Endoscopic Irrigation/Suction System	21 CFR 876.1500	2
Protego Air Water Bottle Tubing	1	OCX – Endoscopic Irrigation/Suction System	21 CFR 876.1500	2
Protego Hybrid Tubing	1	OCX – Endoscopic Irrigation/Suction System	21 CFR 876.1500	2

The Air Water Connector is used in conjunction with air water bottle tubing or hybrid tubing, intended to supply air/CO2 and water during gastro-intestinal endoscopic procedure. It is connected to the air/water port of the endoscope to provide connection from the air/water bottle tubing to the endoscope. The Air Water Bottle Tubing is connected to the air/water port of the endoscope and the sterile water bottle to supply air/ CO2 or sterile water during the GI endoscopic procedure. The Hybrid Tubing is composed of air/water bottle tubing and irrigation tubing, which is intended to connect an air/CO2 source, a sterile water source (water bottle), and an endoscope to supply air/CO2 and water during gastro-intestinal endoscopic procedure.

7. Indications for Use:

The single use Protego Air Water Connector is intended to connect an air/CO2 source, a sterile water source and an endoscope to supply air/CO2 and water during gastrointestinal endoscopic procedures.

Protego Air Water Bottle Tubing is to connect an air/CO2 source, a sterile water source (water bottle), and an endoscope to supply air/CO2 and water during gastrointestinal endoscopic procedures. It is a 24-hour multi-patient use device.

Protego Hybrid Tubing is intended to connect an air/CO2 source, a sterile water source and an endoscope to supply air/CO2, water and irrigation during endoscopic procedures in conjunction with an irrigation pump. It is a 24-hour multi-patient use device.

8. Technological Characteristics

Table 2.1 and Table 2.2 summarizes the subject devices technological characteristics as compared to the predicate devices.

Table 2.1 Summary of design, features and principles of operation and technological characteristics between the Air Water Connector, Air Water Bottle Tubing and predicate device

Specification	Primary Predicate Device	Subject Device	Subject Device	Substantial Equivalence
Device name	Andorate Air Water Bottle Tubing (GAR025)	Protego Air Water Connector (201001)	Protego Air Water Bottle Tubing (202001)	N/A
K number	K191366	K231602	K231602	N/A
Manufacturer	GA Health Company Limited	GA Health Company Limited	GA Health Company Limited	N/A
Product code	OCX	OCX	OCX	Identical
Regulatory Classification	2	2	2	Identical
Regulation No	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.1500	Identical
Regulation Description	Endoscopic Irrigation/Suction System	Endoscopic Irrigation/Suction System	Endoscopic Irrigation/Suction System	Identical
Intended Use	The Air/Water Bottle Tubing is to connect an air/CO2 source, a sterile water source (water bottle), and an endoscope to supply air/CO2 and water during gastrointestinal endoscopic procedures. It is a 24-hour multi-patient use device.	The single use Protego Air Water Connector is intended to connect an air/CO2 source, a sterile water source and an endoscope to supply air/CO2 and water during gastrointestinal endoscopic procedures.	Protego Air Water Bottle Tubing is to connect an air/CO2 source, a sterile water source (water bottle), and an endoscope to supply air/CO2 and water during gastrointestinal endoscopic procedures. It is a 24-hour multi-patient use device.	Substantial Equivalent
Environment of Use	Hospital and or clinics	Hospital and or clinics	Hospital and or clinics	Identical
Single Use or Reusable	24-hour Use	Single Use	24-hour Use	Identical
Material	Acrylonitrile butadiene styrene, Silicone Rubber, Polyoxymethylene, Polyvinyl chloride, Thermoplastic elastomers,	Polycarbonate, Silicone Rubber	Acrylonitrile butadiene styrene, Silicone Rubber, Polyoxymethylene, Polyvinyl chloride, Polycarbonate, Polyethylene	Substantial Equivalent

Specification	Primary Predicate Device	Subject Device	Subject Device	Substantial Equivalence
Device name	Andorate Air Water Bottle Tubing (GAR025)	Protego Air Water Connector (201001)	Protego Air Water Bottle Tubing (202001)	N/A
K number	K191366	K231602	K231602	N/A
Manufacturer	GA Health Company Limited	GA Health Company Limited	GA Health Company Limited	N/A
	Polycarbonate, Polyethylene			
Manufacturing method	Injection molding, Compression molding, Extrusion	Injection molding, Compression molding	Injection molding, Compression molding, Extrusion	Substantial Equivalent
Packaging	Packaged in a sealed pouch	Packaged in a sealed pouch	Packaged in a sealed pouch	Substantial Equivalent
Sterilization	Yes	Yes	Yes	Substantial Equivalent
Shelf Life	3 years	3 years	3 years	Substantial Equivalent

Table 2.2 Summary of design, features and principles of operation and technological characteristics between the Hybrid Tubing and predicate device

Specification	Secondary Predicate Device	Subject Device	Substantial Equivalence
Device name	ENDOGATOR™ Endoscopic Disposable Tubing Kit (100602)	Protego Hybrid Tubing (203001)	N/A
K number	K102855	K231602	N/A
Manufacturer	BYRNE MEDICAL, INC.	GA Health Company Limited	N/A
Product code	OCX	OCX	Identical
Regulatory Classification	2	2	Identical
Regulation No	21 CFR 876.1500	21 CFR 876.1500	Identical
Regulation Description	Endoscopic Irrigation/Suction System	Endoscopic Irrigation/Suction System	Identical
Intended Use	The Universal Irrigation Solution Hybrid (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water and to supply air (via an air pump) along with sterile water during GI endoscopic procedures when used in conjunction with an irrigation pump or cautery unit.	Protego Hybrid Tubing is intended to connect an air/CO2 source, a sterile water source and an endoscope to supply air/CO2, water and irrigation during endoscopic procedures in conjunction with an irrigation pump. It is a 24-hour multi-patient use device.	Substantial Equivalent

Specification	Secondary Predicate Device	Subject Device	Substantial Equivalence
Device name	ENDOGATOR™ Endoscopic Disposable Tubing Kit (100602)	Protego Hybrid Tubing (203001)	N/A
K number	K102855	K231602	N/A
Manufacturer	BYRNE MEDICAL, INC.	GA Health Company Limited	N/A
Environment of Use	Hospital and or clinics	Hospital and or clinics	Identical
Single Use or Reusable	24-hour Use	24-hour Use	Identical
Material	Polycarbonate, Thermoplastic Elastomer, Polyvinyl Chloride, Polyethylene, Methyl methacrylate-acrylonitrile-butadiene-styrene copolymer	Polycarbonate, Silicone Rubber Polyvinyl chloride, Polyoxymethylene, Polyethylene, Acrylonitrile butadiene styrene	Substantial Equivalent
Manufacturing method	Injection molding, Compression molding, Extrusion	Injection molding, Compression molding, Extrusion	Substantial Equivalent
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 on the subject device – endoscope compatibility test, connector pulling force test, connector/tubing pulling force test and backflow prevention test for air water connector, air flow test, air leak test, water flow test, water leak test and bottle cap compatibility test for air water bottle tubing and air flow test, water flow test, air leak test, water leak test, flow clamp test and backflow prevention test for hybrid tubing. 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 all the subject devices are 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.