March 5, 2021

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

Re: K202838
Trade/Device Name: Andorate Universal Endoscope Tip Guard
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCU
Dated: January 15, 2021
Received: January 28, 2021

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,

for
Shanil Haugen
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)*
K202838

Device Name
Andorate® Universal Endoscope Tip Guard

Indications for Use *(Describe)*
The Universal Endoscope Tip Guard is intended to protect tip of the endoscope during transport and storage. It is not intended for use during sterilization.

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

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
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Senior Product Compliance Specialist
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Email: rainy@gahealth.net

3. Date Prepared

5 Mar 2021

4. Device Identification

Device Name:	Andorate® Universal Endoscope Tip Guard
Common Name:	Tip guard for endoscope
Classification Number:	21 CFR 876.1500
Classification Name:	Endoscope and accessories.
Product Code:	OCU
Product Code Name:	Endoscopic Storage Cover
Regulatory Class:	2
Device Panel	Gastroenterology/Urology

5. Predicate Device Identification

Predicate Device 510(k) No.:	K191011
Predicate Device Trade Name:	Scope ProTech
Predicate Device Product Code:	OCU – Endoscopic Storage Cover

6. Device Description:

The Andorate® Universal Endoscope Tip Guard is intended for single use. The universal endoscope tip guard is used to cover distal end of an endoscope prior to transportation and storage. The universal endoscope tip guard is individually packed in sealed package, and it is available both non-sterile and sterile.

7. Indications for Use:

The Universal Endoscope Tip Guard is intended to protect tip of the endoscope during transport and storage. It is not intended for use during sterilization.

8. Technological Characteristics

Table 2 summarizes the universal endoscope tip guard 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	OCU	OCU	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
Endoscope Sizes	Small: 2.7mm – 8mm Large: 8.8mm – 14.7mm	2.5mm – 14mm	Substantial Equivalent
Indications for Use	The Scope ProTech is a single-use, sterile endoscopic tip protector that is intended to be used during the transport and storage of endoscopes for the protection of these delicate instruments. The Scope ProTech is intended for the protection of the distal tip and the bending rubber of endoscopes with a diameter of 2.7mm-8.0mm and 8.7mm-14.7mm. The Scope ProTech will aid in the protection of distal end, the lens and other delicate components from damage. It is not intended for use during sterilization.	The Universal Endoscope Tip Guard is intended to protect tip of the endoscope during transport and storage. It is not intended for use during sterilization.	Substantial Equivalent
Environment of Use	Hospital and or clinics	Hospital and or clinics	Identical
Single Use or Reusable	Single Use	Single Use	Identical
Material	Polypropylene	Silicone Rubber and High-Density Polyethylene	Substantial Equivalent
Manufacturing method	Injection molding	Injection molding	Identical
Packaging	Packaged in a sealed pouch	Packaged in a sealed pouch	Identical

Sterilization	Yes, EO gas, also supplied non-sterile	Yes, EO gas	Substantial Equivalent
Shelf Life	3 years	1 year	Substantial Equivalent

9. Performance Test

The bench testing was performed to support substantial equivalence on both the subject device and the predicate device. The performance data demonstrated that the subject devices met established specifications such as compression test and endoscope compatibility test.

10. 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 non-patient contact device. Notwithstanding its nonpatient contact nature, biocompatibility testing is conducted on subject device GAR107-S in accordance with the ISO 10993 standard similar with mucosal membrane contact for a limited duration (not more than 24 hours). The test result shows that both the subject devices are biocompatible.

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.