December 30, 2020

Apollon Co., Ltd.
% Hyeyoung Moon
Assistant Manager
TSD Life Sciences Co., Ltd.
211, Mallijae-ro, Jung-gu
Seoul, 04508
Korea

Re: K201776
Trade/Device Name: Two-way and Three-way Disposable Silicone Foley Catheters
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZL
Dated: November 24, 2020
Received: November 24, 2020

Dear Hyeyoung Moon:

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 and Part 809); 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,

Sharon M. Andrews
Director
DHT3B: Division of Reproductive,
Gynecology and Urology 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)*
K201776

Device Name
Two-way and Three-way Disposable Silicone Foley Catheters

Indications for Use *(Describe)*
Two-way and Three-way Disposable Silicone Foley Catheters are indicated for urethral catheterization for bladder drainage for urological use only. The Two-way and Three-way Disposable Silicone Foley Catheters have an indwell time of no more than 30 days and are indicated for adult use only.

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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APOLLON Co.,Ltd.

510(k) Summary – K201776

[21 CFR 807.92]

1. Submitter Information

Company Name	:	APOLLON Co., Ltd.
Company Address	:	M-1804/3203, 32, Songdogwahak-ro, Yeonsu-gu, Incheon, Korea
Company Phone	:	+82-32-830-4724
Contact Person	:	Donghyuk Shin/ General Manager dhshin@apollonmds.com
Submission Correspondent	:	Hyeyoung.moon/RA Hyeyoung.moon@tsdls.co.kr Tel: +82-70-4224-9790
Date Prepared	:	December 28, 2020

2. Device Name

Trade Device Name	:	Two-way and Three-way Disposable Silicone Foley Catheters
Common Name	:	Foley Catheter
Classification Name	:	Urological Catheter and Accessories
Classification Number	:	876.5130
Regulatory Class	:	II
Product code(s)	:	EZL
Product code Name	:	Catheter, Retention Type, Balloon
Advisory Panel	:	Gastroenterology/Urology

3. Predicate Device

510(k) Number	: K130908:
Device Name	: Disposable Silicone Foley Catheter
Product Code	: EZL
Manufacturer	: Guangdong Baihe Medical Technology Co., Ltd.

The predicate device is not the subject of a design related recall.

4. Device Description:

This product is a Foley Balloon Catheter. It is a 'prescription only' device. It consists of a Manifold part and Shaft parts. The Manifold Part is equipped with a non-return valve for inflating the balloon and a band to fix the non-return valve and identify the catheter's size by its color. The Shaft parts have an x-ray opaque line for checking the position of the catheter by X-ray and a balloon to place the catheter in the bladder. After the catheter is inserted, distilled water or saline is injected to expand the balloon and fix the catheter in place. The shaft also contains drainage eyes for urine drainage, and a rounded tip to aid insertion of the catheter. This Foley Balloon Catheter will be provided in Two and Three-Way configurations. The Three-Way configuration contains an 'Irrigation Manifold' for washing the bladder with saline solution. The shaft and

APOLLON Co.,Ltd.

510(k) Summary – K201776

[21 CFR 807.92]

balloon of the catheter are made of silicone and zinc oxide. The tip and the manifold are made of silicone only.

The proposed device is supplied in French sizes ranging from 12 to 24. It is available in 337(±15) mm and 345(±15) mm lengths with various balloon sizes. The devices for adults only.

5. Indication for use

Two-way and Three-way Disposable Silicone Foley Catheters are indicated for urethral catheterization for bladder drainage for urological use only. The Two-way and Three-way Disposable Silicone Foley Catheters have an indwell time of no more than 30 days and are indicated for adult use only.

6. Comparison of Technological Characteristics with Predicate Device

Features	Subject Device	Predicated Device
Device name	**Two-way and Three-way Disposable Silicone Foley Catheters**	**Disposable Silicone Foley Catheter**
510(k) Number	K201776	K130908
Manufacturer	APOLLON Co., Ltd.	Guangdong Baihe Medical Technology Co., Ltd.
Indication for use	Two-way and Three-way Disposable Silicone Foley Catheters are indicated for urethral catheterization for bladder drainage for urological use only. The Two-way and Three-way Disposable Silicone Foley Catheters have an indwell time of no more than 30 days and are indicated for adult use only.	Two-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage for urological use only; the indwell time of the proposed device is no more than 30 days. Three-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage and bladder irrigation for urological use only; the indwell time of the proposed device is no more than 30 days.
Population	Male and female (adult only)	Pediatric, male and female
Lumen	Two way and three way	Two way and three way
Indwell Time	No more than 30 days	No more than 30 days
Single Use	Yes	Yes
Size Range	Two way: 12,14,16,18,20,22,24Fr Three way: 14,16,18,20,22,24Fr	Two way: 6,8,10,12,14,16,18,20,22,24 and 26Fr Three way: 16,18,20,22,24 and 26Fr
Length	337(±15) and 345(±15) mm	310mm and 400mm
Balloon	Yes	Same
Balloon size	5cc and 30cc	1.5cc,3cc,5cc,10cc,15cc,20cc,30cc
Sterile	Yes	Same
Main Shaft Material	Silicone and Zinc Oxide	Silicone

APOLLON Co.,Ltd.

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[21 CFR 807.92]

Eyes in Tip	Yes	Same
Tip Shape	Rounded	Same
Performance test	ASTM F623-99	Same

The subject and predicate device have the same intended use. As evidenced by the above table, the subject and predicate device have different technological characteristics. The differences in technological characteristics do not raise different questions of safety or effectiveness.

7. Summary of Testing Performed

The sponsor provided the following performance testing to support substantial equivalence:

- Biocompatibility per ISO 10993 – cytotoxicity, sensitization, irritation or intracutaneous reactivity, material-mediated pyrogenicity, acute systemic toxicity, subacute toxicity, and implantation
- Sterilization validation per ISO 11135:2014
- Shelf-life – transportation simulation, package integrity and functional testing
- Performance/Functional testing per ASTM F623

The protocol and results of the provided performance testing is acceptable.

8. Conclusion

The subject device is substantially equivalent to the predicate device.