November 6, 2019

Biosensors International Pte. Ltd.
Jane Chen Jiayan
Junior Associate, Regulatory Affairs
36 Jalan Tukang
619266 Singapore
Singapore

Re: K182463
Trade/Device Name: Silicone Foley Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: September 18, 2019
Received: September 25, 2019

Dear Jane Chen Jiayan:

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
Glenn B. Bell, Ph.D.
Assistant 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)*
K182463

Device Name
Silicone Foley Catheter

Indications for Use *(Describe)*
This product is used for temporary urethral catheterization or indwelling catheterization and bladder irrigation.

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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Section 5: 510(k) Summary

[As required by section 807.92(c)]

Silicone Foley Catheter (K182463)

1. Applicant Information

Company Name:	Biosensors International Pte Ltd
Company Address:	36 Jalan Tukang, Singapore 619266
Establishment Number:	2084493
Contact Person:	Jane Chen Jiayan Manager, QA/RA Phone: +65 6213 5777 (Ext: 735) Fax: +65 6213 5737 Email: ja.chen@biosensors.com
Date Prepared:	06 Nov 2019

2. Device Name and Classification

Trade Name:	Silicone Foley Catheter
Regulation Number:	21 CFR 876.5130
Regulation Name:	Urological Catheter and Accessories
Regulatory Class:	II
Common Name:	Catheter, Retention Type, Balloon
Product Code:	EZL

3. Predicate Device

Disposable Silicone Foley Catheter (K130908)

4. Device Description

The Silicone Foley Catheter uses the pressure of the bladder to excrete urine. The balloon of the catheter can be inflated and fixed the catheter in place after being injected with a sterile liquid. Foley catheter (2-way) can be used for bladder drainage, and Foley catheter (3-way) also can be used for bladder irrigation.

Female type Foley Catheter is equipped with the advancer which can be used instead of tweezers during the catheterization.

The Silicone Foley Catheter is for single use, is intended for short-term (less than 14 days) use, and is provided with sterile.

Intended population: Pediatric, Male and Female

5. Indications for Use

This product is used for temporary urethral catheterization or indwelling catheterization and bladder irrigation.

6. Summary of Technological Characteristics of Device in relation to Predicate Device

The technology of Biosensors Silicone Foley Catheter (K182463) is substantially equivalent to the Disposable Silicone Foley Catheter manufactured by Guangdong Baihe Medical Technology Co.,Ltd (K130908), with similar indications for use and design construction. The safety and effectiveness of Biosensors Silicone Foley Catheter have been assessed and discussed further in section 7 below.

Comparison between Subject Device and Predicate Device:

	Subject Device – K182463	**Predicate Device – K130908**
Common Name	Catheter, Retention Type, Balloon	Same
Product Code	EZL	Same
Regulation Number	876.5130	Same
Class	II	Same
Population	Pediatric, male and female	Same
Indications for Use	This product is used for temporary urethral catheterization or indwelling catheterization and bladder irrigation.	Similar
French Size	6 – 30 Fr	Similar
Length	410 ± 10mm	310mm and 400mm
Lumen	Two-way and Three-way	Same
Balloon	Yes	Same
Balloon Size	5ml, 5-15ml, 20-30ml, 30ml	1.5ml, 3ml, 5ml, 10ml, 15ml, 20ml, 30ml
Single Use	Yes	Same
Sterile	Yes	Same
Main Shaft Material	Silicone	Same
Validity Period	2 Years	Same
Indwelling Time	No more than 14 days	No more than 30 days
Use with Accessory	Yes	No

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7. Description of Non-Clinical Testing

Testing includes:

- Bench testing of the functional performance
- Biocompatibility testing
- Sterilization validation
- Shelf life validation
- Simulation Shipment validation.

Standards applied to Non-clinical Testing includes:

- Functional performance testing: ASTM F623-99(2013), ISO 2859-1:1999, ISO 8536-4:2010, USP
- Biocompatibility testing:
  ISO 10993-3: 2014 Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
  ISO 10993-5:2009 Part 5: Tests for in vitro cytotoxicity
  ISO 10993-6: 2016 Part 6: Tests for local effects after implantation
  ISO 10993-10: 2010 Part 10: Tests for irritation and skin sensitization
  ISO 10993-11: 2017 Part 11: Tests for systemic toxicity
- Sterilization validation: ISO 11135: 2014, ISO11138-1:2017, ISO 11138-2:2017, ISO 10993-7: 2008/AC:2009, ISO 11737-1:2018, ISO 11737-2: 2009
- Shelf life and simulation shipment validation: ASTM F623-99(2013), ASTMF88/F88M-15, ASTMF1929-15, ASTM F1886/F1886M-16, ISO 11135-2014, EN ISO11607-1:2017, EN ISO11607-2:2017

Results demonstrate that the device is safe and effective in meeting user requirements in accordance with its intended use.

8. Description of Clinical data

Clinical Data includes:

- Clinical Evaluation Report, CER-FC-001(A2)
- Silicone Foley Catheter Post Market Clinical Follow-Up Study, PMCF-2018-01(A1)
- Validation protocol and report for simulation model test of Silicone Foley Catheter – Advancer, VPFC-2018-009(01) and TRFC-2018-009 (01)
- Clinical Data – Evaluation Form of Silicone Foley Catheter

Results of Clinical evaluation, simulation model test with advancer and Clinical Data demonstrate the safety and the effectiveness of Silicone Foley Catheter and using with the accessory – Advancer.

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9. Conclusion

The Silicone Foley Catheter has the similar intended use, technological characteristics and performance characteristics as its predicate device. Performance test results demonstrate that the subject device meets its intended use. It is for these reasons that the subject device can be found substantially equivalent with its predicate device.

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