January 10, 2019

Safe Medical Design
% Allison Komiyama, PhD, RAC
Principal Consultant
AcKnowledge Regulatory Strategies, LLC
2251 San Diego Avenue, Suite B-257
San Diego, CA 92110

Re: K182635
Trade/Device Name: Signal Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZL
Dated: December 12, 2018
Received: December 13, 2018

Dear Allison Komiyama:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark R. Kreitz -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*

K182635

Device Name

Signal Catheter

Indications for Use *(Describe)*

The Signal Catheter is indicated for urological bladder drainage, with a maximum patient indwelling time of 29 days.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SMD
SAFE MEDICAL DESIGN

510(k) Summary
K182635

DATE PREPARED
January 9, 2019

MANUFACTURER AND 510(k) OWNER
Safe Medical Design
2722 Fulton Street, San Francisco, CA 94118, USA
Telephone: +1 (650) 269-0048
Official Contact: Raymond "Buzz" Bonneau, President

REPRESENTATIVE/CONSULTANT
Allison C. Komiyama, Ph.D., R.A.C.
Lucie Dalet, Ph.D.
AcKnowledge Regulatory Strategies, LLC
Telephone: +1 (619) 458-9547
Email: akomiyama@AcKnowledge-RS.com

DEVICE INFORMATION

Proprietary Name/Trade Name:	Signal Catheter
Common Name:	Catheter, Retention Type, Balloon
Regulation Number:	21 CFR 876.5130
Regulation Name:	Urological Catheter and Accessories
Class:	II
Product Code:	EZL
Premarket Review:	ODE/DRGUD/ULDB
Review Panel:	Gastroenterology/Urology

PREDICATE DEVICE IDENTIFICATION
The Signal Catheter is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K172422	Kohli Urinary Drainage Catheter/Nellie Medical, LLC	✓
K941488	Devmed Double Balloon Urological Catheter/Medical Technology Development Corp.	

The predicate devices have not been subject to a design related recall.

DEVICE DESCRIPTION
The Signal Catheter is a 16 French, 2-way silicone Foley catheter, designed to be inserted into the bladder through the urethra to drain urine. The unique signal balloon included in the catheter hub is designed to inflate during excessive pressure in the retention balloon. This

typically occurs when the retention balloon is constricted and cannot be inflated at the nominal inflation pressure of the catheter. In this case, the signal balloon inflates to alleviate the fluid and resulting pressure in the retention balloon.

INDICATIONS FOR USE

The Signal Catheter™ is indicated for urological bladder drainage, with a maximum patient indwelling time of 29 days.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

SMD believes that the Signal Catheter is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has similar dimensions, and uses similar materials as the devices cleared in K172422 and K941488. The subject device has the same intended use and similar technological characteristics (two-way silicone catheter with retention balloon for bladder drainage) to the devices cleared in K172422. The main difference with the devices cleared in K172422 and K941488 is the addition of a non-patient contacting signal balloon in the catheter hub. The signal balloon is designed to alleviate the pressure in the retention balloon when it is constricted and cannot be inflated at the nominal inflation pressure of the catheter. This technological characteristic has undergone testing to ensure that the device is substantially equivalent to the predicates.

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate safety based on current industry standards:

Biocompatibility: Patient contacting material was subjected to biocompatibility testing according to the recommendations of ISO 10993-1 *Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process*

Performance testing: The performance testing of the subject device included dimensional verification, functional and performance testing, and compliance to ASTM F623 *Standard Performance Specification for Foley Catheter* requirements and EN 1616 *Sterile urethral catheters for single use*.

The results of these tests indicate that the Signal Catheter is substantially equivalent to the predicate devices.

SUMMARY OF CLINICAL TESTING

There was no clinical data submitted in order to demonstrate substantial equivalence.

510(k) Summary

CONCLUSION

Based on the testing performed, including biocompatibility testing, dimensional verification, functional and performance testing, and compliance to ASTM F623 and EN 1616 requirements, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed Signal Catheter are assessed to be substantially equivalent to the predicate devices.