January 26, 2018

Halyard Health, Inc.
David M. Lee, JD
Associate Director, Regulatory Affairs
5405 Windward Parkway
Alpharetta, GA 30004

Re: K173955
Trade/Device Name: MIC-KEY* SF Over-the-Wire Stoma Measuring Device
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT
Dated: December 26, 2017
Received: December 28, 2017

Dear David M. Lee:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Benjamin R. Fisher -S

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)*
K173955

Device Name
MIC-KEY* SF Over-the-Wire Stoma Measuring Device

Indications for Use *(Describe)*
MIC-KEY* SF Over-the-Wire Stoma Measuring Device is indicated for measuring the length of a stoma prior to placement of a low profile feeding tube.

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- K173955

Date: January 20, 2018

Applicant's Name, Address, Telephone, Contact Person

Halyard Health, Inc.
5405 Windward Parkway
Alpharetta, Georgia 30004

Contact Name: David M. Lee, JD
Associate Director, Regulatory Affairs
Halyard Health
470 448 5182 (Phone)
David.lee@hyh.com

1. CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification:	Class II, per 21 CFR 876.5980
Classification Name:	Gastrointestinal tube and accessories
Common/Usual Name:	Stoma Measuring Device
Product Code:	KNT
Trade Name:	MIC-KEY* SF Over-the-Wire Stoma Measuring Device

2. PREDICATE DEVICE

MIC-KEY* SF Over the Wire Stoma Measuring Device cleared under the MIC-KEY*LOW PROFILE GASTROSTOMY TUBE AND ACCESSORIES-K122653.

3. INDICATIONS FOR USE

MIC-KEY* SF Over-the-Wire Stoma Measuring Device is indicated for measuring the length of a stoma prior to placement of a low profile feeding tube.

4. DESCRIPTION OF DEVICE

MIC-KEY* SF Over-the-Wire Stoma Measuring Device is designed for measuring the length of a stoma prior to placement of a low profile feeding tube. The Stoma Measuring Device comprises a tubular shaft 10 Fr with graduated scale, an inflation valve and retaining balloon. The MIC-KEY* SF Over the Wire Stoma Measuring Device is made of polyurethane tubing, EtO sterilized and for single use. Like the predicate device, it is intended to be use in hospital environment.

5. TECHNOLOGICAL CHARACTERISTICS

The MIC-KEY* SF Over-the-Wire Stoma Measuring Device is substantially equivalent to the predicate device. The following changes from the predicate device were made:

- the printed device labeling (printed marking was added to the polyurethane molded head indicating the balloon inflation volume)
- minor changes to the geometry of the molded polyurethane head
- minor change to the geometry of the molded tethered cap
- the ink used for device marking was changed

There are no other significant differences in the design, materials, performance, and technological characteristics from the predicate device.

6. SUMMARY OF NONCLINICAL TESTS

Performance testing on the device under submission was conducted to demonstrate the modified device continued to meet performance specification. Results of design verification and validation activities did not raise any new issues of safety or effectiveness. Non-clinical verification was conducted through the risk management process according to ISO 14971:2012. The following verification tests were conducted:

Test	Acceptance Criterion	Result
Tensile Strength, Head/Tube	≥ 15 N per EN 1615:2000	Pass
Balloon Concentricity	< 2:1 per ASTM F 2528-06	Pass
Deflated Balloon Outer Diameter	Pass through 4 Fr size larger ring gauge per ASTM F 2528-06 (without lubricant)	Pass
Deflated Balloon Outer Diameter	Pass through 2 Fr size larger ring gauge per ASTM F 2528-06 (with lubricant)	Pass
Tube Outer Diameter	Pass through 1 Fr size larger ring gauge per ASTM F 2528-06	Pass
Balloon Valve Luer Tip Compatibility	Able to inflate balloon with a Luer tip syringe	Pass
Printed Ink Durability	Printing remains legible following cleaning	Pass
Device Removal Force	≤ 0.48 lbf	Pass
Balloon System Leak Test	No leakage when the balloon is inflated for five minutes	Pass
Collar Movement	The collar can slide along the tubing for the entire length of the printed ruler	Pass
System Leak Test, Cap/Head	No leakage when pressurized to 0.5 psi	Pass
Guidewire Insertion	Device can slide along a 0.038” diameter guidewire	Pass
Device Radiopacity	ASTM F640–7	Pass
Sterile Barrier	No bubbles per ASTM F 2096-11	Pass

The following biocompatibility tests were also conducted, and all met acceptance criteria:

ISO 10993-1 Fourth edition 2009-10-15 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
AAMI ANSI ISO 10993-5, 2009: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-11:2006/(R2010): Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

7. OVERALL PERFORMANCE CONCLUSIONS

The above nonclinical studies demonstrate MIC-KEY* SF Over-the-Wire Stoma Measuring Device is substantial equivalence to the predicate MIC-KEY* SF Over-the-Wire Stoma Measuring Device **(K122653)** in intended use, design, materials, performance, and biocompatibility attributes. There are no new questions of safety and effectiveness as compared to the predicate device.