November 5, 2018

B. Braun Medical, Inc.
Anita J. Nemeth
Senior Regulatory Affairs Analyst
901 Marcon Boulevard
Allentown, PA 18109

Re: K180801
Trade/Device Name: Actreen® Hi-Lite Intermittent Urinary Catheters
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: GBM
Dated: October 15, 2018
Received: October 16, 2018

Dear Anita J. Nemeth:

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)*

K180801

Device Name
Actreen® Hi-Lite Intermittent Urinary Catheters

Indications for Use *(Describe)*
Actreen® Hi-Lite Intermittent Urinary Catheters are indicated for intermittent urinary catheterization by adult and pediatric patients with chronic urine retention or voiding dysfunction.

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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5. 510(k) SUMMARY

DATE: March 23, 2018

SUBMITTER:
B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
610-266-0500

Contact: Anita J. Nemeth
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DEVICE NAME: Actreen® Hi-Lite Intermittent Urinary Catheters

COMMON NAME: Intermittent Urinary Catheter

DEVICE CLASSIFICATION:
21 CFR §876.5130, Class II
Urological Catheter and Accessories
Classification Product Code: GBM

PREDICATE DEVICE:
510(k) Number: K151772
Device Name: Actreen® Mini Intermittent Urinary Catheters
Classification Product Code: GBM
Regulation Number: §876.5130, Class II
Applicant: B. Braun Medical Inc.

REFERENCE DEVICE:
510(k) Number: K141642
Device Name: VaPro™ Intermittent Catheter
Classification Product Code: GBM
Regulation Number: §876.5130, Class II
Applicant: Hollister, Incorporated

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The B. Braun Actreen® Hi-Lite Intermittent Urinary Catheters include the Actreen® Hi-Lite Cath and Actreen® Hi-Lite Set. The Actreen® Hi-Lite Set is identical to the Actreen® Hi-Lite Cath, except that the Actreen® Hi-Lite Set includes a urine collection bag which is pre-attached to the catheter. The proposed devices are flexible tubular devices that are inserted through the urethra and used to pass fluids from the urinary tract. The Actreen® Hi-Lite Intermittent Urinary Catheters are offered in a 14.5 inch length, a variety of gauge sizes and straight or curved tip configurations to accommodate the individual anatomy of both male and female users. The outer packaging was designed to facilitate easier, no touch access for those with limited dexterity, while the hydrophilic lubrication makes this single use catheter ready to use.

INDICATIONS FOR USE

Actreen® Hi-Lite Intermittent Urinary Catheters are indicated for intermittent urinary catheterization by adult and pediatric patients with chronic urine retention or voiding dysfunction.

SUBSTANTIAL EQUIVALENCE

B. Braun Medical Inc. Actreen® Hi-Lite Intermittent Urinary Catheters are substantially equivalent to the Actreen® Mini Intermittent Urinary Catheters (K151772) predicate devices having similar intended use, technological properties, and performance.

The Actreen® Hi-Lite Intermittent Urinary Catheter differs from the predicate device in that the Actreen® Hi-Lite Intermittent Urinary Catheter is available in a longer length, additional gauge sizes and straight or curved tip configurations to accommodate the individual anatomy of both male and female users. The predicate device is offered in a 3.5 inch straight catheter tube length in French gauge sizes ranging from 10-14, whereas the proposed device is offered in a 14.5 inch catheter tube length with straight or curved tip options and French gauge sizes ranging from 8-18 for the catheter and French gauge sizes from 10-18 for the set. Additionally, the pre-attached urine collection bag on the predicate device is designed to hold a volume up to 700mL, while the proposed device collection bag holds a volume up to 1000mL.

Intended Use

The Actreen® Hi-Lite Intermittent Urinary Catheters have similar intended use to the predicate devices. Both the proposed device and the predicate device are intended for intermittent urinary catheterization.

Technical Characteristics

The predicate devices and proposed are comprised of the same materials, with the exception of one material of the primary packaging of the catheter. They include the same components, the same general design and have similar technological characteristics. Both are made of thermoplastic polyolefin (TPO) catheter tubing which is pre-lubricated with a hydrophilic lubricant, and include smooth, oval eyelets designed to minimize friction. The proposed Actreen® Hi-Lite Intermittent Urinary Catheters are available in similar gauge sizes as the Actreen® Mini Intermittent Urinary Catheters. The Actreen® Hi-Lite Set and Actreen® Mini Set both come with a pre-attached polyethylene/polypropylene urine collection bag and both contain an "anti-reflux valve**"** that allows urine to flow into the bag, but not back out of the bag into the catheter.

Performance Data

Biocompatibility and performance testing were performed to support substantial equivalence of the subject devices to the predicate devices. Biocompatibility testing was performed in accordance with ISO 10993-1. Performance testing was performed according to EN 1616: 1997 Sterile Urethral Catheters for Single Use.

Table 5.1 summarizes the comparison between the Actreen® Hi-Lite Intermittent Urinary Catheters and the Actreen® Mini Intermittent Urinary Catheters.

Table 5.1 Device Comparison Table		
Item	**Proposed Device: KXXXXXX** **Product code: GBM** **Actreen® Hi-Lite Cath** **Actreen® Hi-Lite Set**	**Predicate Device: K151772** **Product code: GBM** **Actreen® Mini Cath** **Actreen® Mini Set**
Intended Use	Intermittent urinary catheterization	Intermittent urinary catheterization
Indications for Use	Actreen® Hi-Lite Intermittent Urinary Catheters are indicated for intermittent urinary catheterization by adult and pediatric patients with chronic urine retention or voiding dysfunction.	Actreen® Mini Intermittent Urinary Catheters are indicated for intermittent urinary catheterization by female patients with chronic urine retention or voiding dysfunction.
Description	The Actreen® Hi-Lite Cath and Actreen® Hi-Lite Set are sterile, single use, disposable catheters designed for use by male or female patients. Once removed from the package, the catheters are ready to use and are pre- lubricated with a hydrophilic lubrication. They are available in one length, with a straight or curved tip configuration to accommodate the individual anatomy of both male and female users. The catheter is available in six gauges sizes, while the set is available in five gauge sizes. The Actreen® Hi-Lite Set includes a pre-attached urine collection bag.	The Actreen® Mini Cath and Actreen® Mini Set are sterile, single use, disposable catheters designed for use by females. Once removed from the package the catheters are ready to use and are pre- lubricated with a hydrophilic lubrication. They are available in one length with a straight tip. The Actreen® Mini Set includes a pre-attached urine collection bag.
Dimensions	**Catheter:** 14.5 inch straight or curved tip catheter tube length, French sizes 08, 10, 12, 14, 16, 18 **Set:** 14.5 inch straight or curved tip catheter tube length, French sizes 10, 12, 14, 16, 18 Actreen® Hi-Lite Set urine collection bag volume: 1000mL	**Catheter/Set:** 3.5 inch straight catheter tube length, French sizes 10, 12, 14 Actreen® Mini Set urine collection bag volume: 700mL
Materials	Catheter tube : Thermoplastic Polyolefin (TPO) Lubricant : hydrophilic lubricant Connector : EVA Connector glue : Acrylate UV or Cyanoacrylate Actreen® Hi-Lite Cath primary packaging : Polyethylene, Polypropylene Actreen® Hi-Lite Set primary packaging and collection bag : Polyethylene, Polypropylene	Catheter tube : Thermoplastic Polyolefin (TPO) Lubricant : hydrophilic lubricant Connector : EVA Connector glue : Acrylate UV or Cyanoacrylate Actreen® Mini Cath primary packaging : Polyethylene Actreen® Mini Set primary packaging and collection bag : Polyethylene, Polypropylene
General Performance Requirements	EN 1616 : 1997 - Sterile Urethral Catheters for Single Use.	EN 1616 : 1997 - Sterile Urethral Catheters for Single Use.
Biocompatibility	In accordance with ISO 10993-1 Classification: surface-contacting devices - mucosal membrane Contact Duration: prolonged exposure and a duration of use greater than 24 hours but less than 30 days.	In accordance with ISO 10993-1 Classification: surface-contacting devices - mucosal membrane Contact Duration: prolonged exposure and a duration of use greater than 24 hours but less than 30 days.
Sterilization Process	Beta Irradiation (E-beam)	Beta Irradiation (E-beam)

CONCLUSION

Based on the results of biocompatibility and performance testing, the proposed B. Braun Medical Actreen® Hi-Lite Intermittent Urinary Catheters are considered substantially equivalent to the predicate devices.