May 7, 2020

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

Re: K192577
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: April 6, 2020
Received: April 6, 2020

Dear Ms. 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/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,

Purva Pandya
Acting 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)*

K192577

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.

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5. 510(k) SUMMARY

DATE: September 18, 2019

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: K180801
Device Name: Actreen® Hi-Lite Intermittent Urinary Catheters Classification Product Code: GBM
Regulation Number: §876.5130, Class II
Applicant: B. Braun Medical Inc.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The proposed B. Braun Actreen® Hi-Lite Intermittent Urinary Catheter devices are flexible tubular devices that are inserted through the urethra and used to pass fluids from the urinary tract. These Actreen® Hi-Lite Intermittent Urinary Catheters are offered in a 7.5 inch length with a variety of French gauge sizes ranging from 6-16 with a straight tip. 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

The proposed 7.5 inch Actreen® Hi-Lite Intermittent Urinary Catheters are substantially equivalent to the Actreen® Hi-Lite Intermittent Urinary Catheters (K180801) predicate device having the same intended use, technological properties, and performance.

The 7.5 inch Actreen® Hi-Lite Intermittent Urinary Catheters differ from the predicate device in that the proposed Actreen® Hi-Lite Intermittent Urinary Catheters are available in a shorter length, an additional gauge size and only the straight tip configuration. The predicate device is offered in a 14.5 inch catheter tube length with French gauge sizes ranging from 8-18 and straight or curved tip configurations, whereas the proposed device is offered in a 7.5 inch catheter tube length with a straight tip and French gauge sizes ranging from 6-16. Additionally, the predicate device offered a set option designed with a pre-attached urine collection bag, while the proposed device is available with the catheter only at this time.

Intended Use

The 7.5 inch Actreen® Hi-Lite Intermittent Urinary Catheters have the same intended use as the predicate devices. Both the proposed devices and the predicate devices are intended for intermittent urinary catheterization by adult and pediatric patients.

Technical Characteristics

The predicate and proposed devices are comprised of the same materials. They include the same components, the same design and have the same 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 with a shorter length than the predicate Actreen® Hi-Lite Intermittent Urinary Catheters.

Performance Data

Biocompatibility and design verification performance testing were performed which support substantial equivalence of the subject devices to the predicate devices. Biocompatibility testing was performed in accordance with ISO 10993-1: 2009. Design verification performance testing was performed according to EN 1616: 1997 Sterile Urethral Catheters for Single Use.

Table 5.1 summarizes the comparison of the proposed Actreen® Hi-Lite Intermittent Urinary Catheters and the predicate Actreen® Hi-Lite Intermittent Urinary Catheters.

Table 5.1 Device Comparison Table		
Item	**Proposed Device: KXXXXXX** **Product code: GBM** **Actreen® Hi-Lite Cath**	**Predicate Device: K180801** **Product code: GBM** **Actreen® Hi-Lite Cath** **Actreen® Hi-Lite 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® Hi-Lite Intermittent Urinary Catheters are indicated for intermittent urinary catheterization by adult and pediatric patients with chronic urine retention or voiding dysfunction.
Description	The Actreen® Hi-Lite Catheters 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 tip configuration only, which accommodates both male and female users. The catheter is available in six gauges sizes. There is no set available at this time.	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.
Dimensions	**Catheter:** 7.5 inch straight tip catheter tube length, French gauge sizes 06, 08, 10, 12, 14, 16	**Catheter:** 14.5 inch straight or curved tip catheter tube length, French gauge sizes 08, 10, 12, 14, 16, 18 **Set:** 14.5 inch straight or curved tip catheter tube length, French gauge sizes 10, 12, 14, 16, 18 Actreen® Hi-Lite Set urine collection bag volume: 1000mL
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	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
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: 2009 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: 2009 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

Results of biocompatibility and performance testing conducted on the proposed Actreen® Hi-Lite Intermittent Urinary Catheters demonstrate that they are substantially equivalent to the predicate device.