DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

February 9, 2016

B. Braun Medical Inc.
Sierra Mertz
Regulatory Affairs Analyst
901 Marcon Blvd.
Allentown, PA 18109

Re: K151772
Trade/Device Name: Actreen® Mini Intermittent Urinary Catheters
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: Class II
Product Code: GBM
Dated: January 20, 2016
Received: January 27, 2016

Dear Sierra Mertz,

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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151772

Device Name
Actreen Mini Intermittent Urinary Catheters

Indications for Use *(Describe)*
Actreen Mini Intermittent Urinary Catheters are indicated for intermittent urinary catheterization by female 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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5. 510(k) SUMMARY

DATE: June 29, 2015

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

Contact: Sierra Mertz
Phone: (610) 266-0500
Fax: (610) 266-4962
E-mail: sierra.mertz@bbraun.com

DEVICE NAME: Actreen® Mini 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: K121457
Device Name: SpeediCath Compact Set
Classification Product Code: GBM
Regulation Number: §876.5130, Class II
Applicant: Coloplast Corp

510(k) Number: K072808
Device Name: SpeediCath Compact
Classification Product Code: GBM
Regulation Number: §876.5130, Class II
Applicant: Coloplast Corp

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The Actreen Mini Intermittent Urinary Catheters include the Actreen Mini Cath and the Actreen Mini Set. The Actreen Mini Set is identical to the Actreen Mini Cath, except that the Actreen Mini Set includes a urine collection bag which is pre-attached to the catheter. The proposed devices are available in one length of 3.5 in with a straight tip, and offered in gauges 10 FR, 12 FR, 14 FR.

INDICATIONS FOR USE

Actreen Mini Intermittent Urinary Catheters are indicated for intermittent urinary catheterization by female patients with chronic urine retention or voiding dysfunction.

SUBSTANTIAL EQUIVALENCE

B. Braun Medical Inc's. Actreen Mini Intermittent Urinary Catheters are substantially equivalent to the predicate devices having similar intended use, technological properties, and performance.

Technical Characteristics

The Actreen Mini Intermittent Urinary Catheters have similar physical and technical characteristics to the predicate devices. The Actreen Mini Intermittent Urinary Catheters are offered in similar sizes and are comprised of similar components to the predicate devices. The proposed devices and predicate devices include a pre-lubricated catheter tube and connector. The Actreen Mini Set and Coloplast SpeediCath Compact Set each include a pre-attached urine collection bag.

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 relevant sections of EN 1616.

CONCLUSION

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