DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 14, 2016

Smith & Nephew Medical Limited
Samantha Neilson
Regulatory Affairs Manager, Advanced Wound Management
101 Hessle Road
Hull, HU3 2BN GB

Re: K153723
Trade/Device Name: Acticoat Surgical Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 22, 2015
Received: December 28, 2015

Dear Samantha Neilson:

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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K153723

Device Name
ACTICOAT Surgical Dressing

Indications for Use *(Describe)*
ACTICOAT Surgical dressing is indicated for use in light to moderately exuding full and partial thickness wounds including decubitus ulcers, diabetic ulcers, surgical wounds, 1st and 2nd degree burns, and donor sites. ACTICOAT Surgical dressing may be used over debrided and full and partial thickness wounds.

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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510(k) SUMMARY

General Information

Submitter Name/ Address: Smith & Nephew Medical Limited

101 Hessle Road,

Hull,

HU3 2BN

United Kingdom

Establishment registration Number: 8043484

Contact Person: Samantha Neilson, Regulatory Affairs Manager

Phone Number: +44 1482 673790

Date Prepared: September 12, 2016

Application Correspondent: Smith & Nephew Medical Limited.

101 Hessle Road,

Hull,

HU3 2BN,

United Kingdom

Contact Person: Samantha Neilson, Regulatory Affairs Manager

Phone Number: +44 1482 673790

Device Description

Trade Name: ACTICOAT Surgical Dressing

Common or Usual Name: ACTICOAT Surgical

Device Classification: Dressing, Wound, Drug

Product Code: FRO

Predicate Device Information

510(k)#	Device	Clearance Date
K050030	ACTICOAT Moisture Control Dressing	Apr 21, 2005
K083113	ACTICOAT Flex 7 Dressing	Jul 22, 2009

Device Description

ACTICOAT Surgical is an absorbent trilaminate antibacterial barrier dressing consisting of a silver-coated polyurethane layer, a white polyurethane foam and an adhesive coated waterproof polyurethane film layer. The device provides an effective antibacterial barrier to reduce or inhibit microbial colonization of the dressing.

Indications for Use

ACTICOAT Surgical dressing is indicated for use in light to moderately exuding full and partial thickness wounds including decubitus ulcers, diabetic ulcers, surgical wounds, 1st and 2nd degree burns, and donor sites. ACTICOAT Surgical dressing may be used over debrided and full and partial thickness wounds.

Comparison between Subject and Predicate Devices

ACTICOAT Surgical antibacterial dressing has the same intended use as both of its predicate devices, namely to serve as a protective wound covering. Accordingly, the device meets the first requirement for a finding of substantial equivalence. The dressing also has similar indications for use as its predicate devices. The main difference between the ACTICOAT Surgical indications and those of the primary predicate ACTICOAT Moisture Control (K050030) is that the subject device is additionally an antibacterial dressing indicated for use in full thickness wounds, diabetic ulcers and surgical wounds. These added indications do not change the intended therapeutic effect of the device, but simply expand the types of wounds for which the device may be used as a protective wound covering. Additionally, the use of a silver protective wound covering for full thickness wounds, diabetic ulcers and surgical wounds is a cleared indication for ACTICOAT Flex 7 (K083113).

ACTICOAT Surgical and ACTICOAT Moisture Control have the same material composition, being comprised of three layers: a polyurethane backing layer, an absorbent polyurethane foam layer, and a silver-coated perforated polyurethane wound contact layer. Ionic silver is used in both devices. The foam layer of the ACTICOAT Surgical dressing has a thickness which is 3 mm less than that of the primary predicate, but this difference does not raise new or different questions of safety or effectiveness.

Non-Clinical Tests (Bench)

The following non-clinical (bench) testing has been carried out:

- Physical properties testing of the subject and predicate devices: demonstrated that the products had comparable results that complied with the physical property parameters of the finished product specification.
- Silver release testing: showed that the subject device and predicate devices released less than 0.5 mg/cm^2 in total over the full seven day period. The results also show that the release profile for ACTICOAT

Surgical is similar to the predicate devices over the seven day period tested.

- Microbiology testing: demonstrated that the subject device can maintain a greater than four log reduction against the following organisms *Pseudomonas aeruginosa, Staphylococcus aureus, Bacteroides fragilis, MRSA, VRE, Escherichia coli, and Acinetobacter baumannii*.

Biocompatibility Testing

ACTICOAT Surgical has been evaluated according to the Biological Evaluation of Medical Devices Standard BS EN ISO 10993, with particular reference to Part 1 (2009): Evaluation and testing within a risk management process. The assessment demonstrated that ACTICOAT Surgical is safe for use for its intended purpose.

Conclusion

In establishing substantial equivalence to the currently marketed predicate devices, Smith & Nephew Medical Limited evaluated the indications for use, materials, design, product specifications and manufacturing requirements of the device. Performance testing, biocompatibility testing, and microbiology testing has been successfully completed to demonstrate that the subject device ACTICOAT Surgical is substantially equivalent to the predicate devices ACTICOAT Moisture Control and ACTICOAT Flex 7 for the intended use.