



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

August 3, 2016

Smith & Nephew Medical Limited
% Ms. Amy Campbell
Smith & Nephew, Inc.
3909 Hulen St
Fort Worth, Texas 76107

Re: K161289
Trade/Device Name: Durafiber Ag
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 6, 2016
Received: May 9, 2016

Dear Ms. Campbell:

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

Indications for Use

510(k) Number (if known)
K161289

Device Name
DURAFIBER Ag

Indications for Use (Describe)

DURAFIBER Ag is an effective antimicrobial dressing that is intended to provide a moist wound environment for use in the management of partial and full thickness wounds including first and second degree burns. Appropriate wounds types include:

- Chronic wounds including diabetic ulcers, leg ulcers, pressure ulcers and sores (partial & full thickness);
- surgical wounds left to heal by secondary intent;
- traumatic wounds;
- wounds that are prone to minor bleeding, such as wounds that have been mechanically or surgically debrided.

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

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: August 2, 2016

Application Correspondent: Smith & Nephew Inc.
3909 Hulen Street,
Fort Worth,
Texas, 76107,
USA

Contact Person: Amy Campbell, Senior Manager Regulatory Affairs

Phone Number: 1-817-302-3901

Device Description

Trade Name: DURAFIBER™ Ag

Common or Usual Name: Silver Absorbent, Gelling Dressing

Device Classification: Dressing, Wound, Drug

Product Code: FRO

Predicate Device Information

510(k)#	Device	Clearance Date
K103793	DURAFIBER Ag	May 02, 2011

Device Description

DURAFIBER Ag is a non-woven dressing made of cellulose and cellulose ethylsulphonate with silver. The product is an absorbent fibrous dressing that gels on contact with wound fluid. The silver provides the antimicrobial properties intended to reduce or inhibit microbial colonization of the device.

The silver is present in the device in the form of silver chloride. Upon contact with wound fluid, silver ions are produced from the dissociation of silver and chloride atoms. The ionic form of silver is the active antimicrobial agent.

Indications for Use

DURAFIBER Ag is an effective antimicrobial dressing that is intended to provide a moist wound environment for use in the management of partial and full thickness wounds including first and second degree burns. Appropriate wound types include:

- Chronic wounds including diabetic ulcers, leg ulcers, pressure ulcers and sores (partial & full thickness);
- surgical wounds left to heal by secondary intent;
- traumatic wounds;
- wounds that are prone to minor bleeding, such as wounds that have been mechanically or surgically debrided.

Comparison between New and Predicate Devices

The Indications for Use statement for DURAFIBER Ag is identical to the predicate device.

The physical characteristics for both the subject and predicate devices are the same whilst the antimicrobial characteristics for the subject device and predicate are similar. DURAFIBER Ag comprises of a blend of cellulose/ cellulose ethylsulphonte fibres and silver. The primary difference presented between the subject device and the predicate device is a reduction in the amount of silver incorporated into the product. The subject device does not raise any new issues of safety and effectiveness.

The design, materials and manufacturing methods of the subject and predicate devices are the same.

Non-Clinical Tests (Bench)

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

- Physical properties testing of the subject and predicate devices: Results showed that the reduced silver content of the dressing did not alter the physical properties of the dressing.

- Silver release testing: Results showed that the subject device released a lower amount of silver over a seven day test period compared to the predicate device.
- Microbiology testing: Results showed that the reduced silver content of the subject device did not alter the antimicrobial properties of the dressing.

Biocompatibility Testing

DURAFIBER Ag has been evaluated in accordance with ISO 10993-1 and is considered safe for its intended use.

Conclusion

In establishing substantial equivalence to the currently marketed predicate device, Smith & Nephew Medical Limited evaluated the indications for use, materials, design, product specifications and manufacturing requirements of the device. Performance testing, biocompatibility testing assessment, and microbiology testing has been successfully completed to demonstrate that the modified DURAFIBER Ag is substantially equivalent to the predicate device for the intended use.