December 20, 2019

Smith & Nephew Medical Ltd.
Ana Castillo
Senior Regulatory Affairs Specialist
101 Hessle Road
Hull East Riding of Yorkshire, HU3 2BN GB

Re: K190730
Trade/Device Name: IODOSORB
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 1, 2019
Received: October 2, 2019

Dear Ana Castillo:

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,

Kimberly M. Ferlin, Ph.D.
Assistant Director (Acting)
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K190730

Device Name
IODOSORB

Indications for Use *(Describe)*
IODOSORB is indicated for use in managing wet ulcers and wounds such as venous stasis ulcers, pressure sores, and infected traumatic and surgical wounds. IODOSORB assists in wound area protection and in reducing the microbial load in the wound dressing, retards eschar formation and keeps the lesion soft and pliable.

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

510(k) Owner:	Smith + Nephew Medical Ltd 101 Hessle Road Hull East Riding Of Yorkshire, UNITED KINGDOM HU3 2BN
Date Prepared:	December 12, 2019
Submitted by (Contact Person):	Ana Castillo, Regulatory Affairs Specialist II, AWM Smith + Nephew, Inc. T (817) 916-1441 F (817) 302-3983
Name of Device:	IODOSORB°
Common Name:	Beads, Hydrophilic, For Wound Exudate Absorption
Device Classification Name:	Dressing, Wound, Drug
Device Class:	Unclassified
Panel Code:	General & Plastic Surgery
Product Code:	FRO
Predicate Device:	IODOSORB GEL- K905069 The predicate devices have not been subject to a design related recall.

Device Description:

IODOSORB consists of 0.1mm diameter biodegradable spherical hydrophilic beads of cadexomer which incorporate 0.9% weight per weight iodine mixed with polyethylene glycols and poloxamer. The beads are composed of a three dimensional network of macromolecular chains of cross-linked cadexomer which is large enough to allow substances with a molecular weight of less than 1,000 to enter freely. As with all products having these characteristics, substances with a molecular weight of 1000 - 5000 enter the beads less freely, while those with a molecular weight greater than 5000 remain in the interspaces between the beads.

Indications for Use

IODOSORB is indicated for use in managing wet ulcers and wounds such as venous stasis ulcers, pressure sores, and infected traumatic and surgical wounds. IODOSORB assists in wound area protection and in reducing the microbial load in the wound dressing, retards eschar formation and keeps the lesion soft and pliable

Comparison of Technological Characteristics with the Predicate Device

No changes have been made to the product other than labeling changes (e.g. contraindications, precautions/warnings). As the changes to the labeling do not affect the product performance, the product remains substantially equivalent to the predicate device.