December 6, 2019

Sofradim Production
℅ Angela Arsdale
Regulatory Affairs Manager
Covidien
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K192443
Trade/Device Name: Dextile Anatomical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: September 4, 2019
Received: September 6, 2019

Dear Angela Arsdale:

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,

For Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
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)*
K192443

Device Name
Dextile Anatomical Mesh

Indications for Use *(Describe)*
Dextile Anatomical Mesh is intended to be used for the reinforcement of soft tissues where weakness exists during repair of inguinal hernia by laparoscopic approach.

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

Date Prepared:	November 26, 2019
Submitter:	Sofradim Production (subsidiary of Covidien Llc) 116, avenue du Formans 01600 Trevoux, France Telephone: +33 (0)4 74 08 90 00 Fax: +33 (0) 4 74 08 90 02
Contact:	Angela Van Arsdale Regulatory Affairs Manager 60 Middletown Avenue North Haven, CT 06473 Phone: (203) 492-5787 Fax: (203) 492-5029 Email: angela.vanarsdale@medtronic.com
Name of device:	Dextile™ Anatomical Mesh
Trade/Proprietary name:	Surgical Mesh
Common name:	Mesh, Surgical, Polymeric
Classification name:	Panel number and product code: 79 FTL Regulation number: 21 CFR 878.3300
Predicate Device:	3DMAX™ Light Mesh
Trade/Proprietary name:	Surgical Mesh
Common name:	Mesh, Surgical, Polymeric
Classification name:	Panel number and product code: 79 FTL Regulation number: 21 CFR 878.3300
510(k) Number:	K091659
Manufacturer:	Davol Inc., Subsidiary of C.R. Bard, Inc Route 22 West
Device Description:	Dextile™ Anatomical Mesh is designed to be placed in a pre-peritoneal site by laparoscopic approach. The device has an anatomical shape with sealed edges allowing coverage of inguinal hernia defects and facilitating laparoscopic mesh deployment and handling. The mesh is made of a non-absorbable macroporous monofilament polypropylene textile. A green marking is placed on the medial side of the mesh to help positioning and orienting the mesh: “ML” letters designate Medial Line. The green marking is made of monofilament polyester yarn. The “D&C Green No. 6” dye is used for the marking.
Intended Use:	Dextile™ Anatomical Mesh is intended for the reinforcement of soft tissue where weakness exists.

Indications for use:

Dextile™ Anatomical Mesh is intended to be used for the reinforcement of soft tissues where weakness exists during repair of inguinal hernias by laparoscopic approach.

Summary comparing the technological characteristics of the subject and predicate device:

The subject Dextile™ Anatomical Mesh is substantially equivalent to the predicate device 3DMAX™ Light Mesh (K091659) in terms of indications and design for the following technological characteristics:

- Design: anatomical shape of the mesh with sealed edges, presence of a medial marker, three mesh sizes
- Polypropylene textile performance

Materials:

Dextile™ Anatomical Mesh has been evaluated and found compliant with ISO Standard 10993-1.

Performance data:

The following performance data is provided in support of the substantial equivalence determination:

- In vitro (bench) tests have been performed in accordance with the FDA Guidance *"Guidance for the Preparation of a Premarket Notification Application of a Surgical Mesh"* issued March 2, 1999 to evaluate the performance characteristics of the subject Dextile™ Anatomical Mesh in comparison with the predicate 3DMAX™ Light Mesh (K091659). The following mesh characteristics were assessed:
  - Pore size
  - Surface density
  - Thickness
  - Bursting strength
  - Bursting deflection
  - Tensile breaking strength
  - Elongation at break
  - Tear strength
  - Suture pull-out strength

  Trocar passage testing was conducted to demonstrate that the mesh integrity is preserved when used by laparoscopy.

- *In vivo* pre-clinical tests on representative animal model were conducted in comparison with the predicate 3DMAX™ Light Mesh (K091659) to evaluate the tissue integration. Results demonstrate that no difference was observed between the subject Dextile™ Anatomical Mesh and the predicate 3DMAX™ Light Mesh (K091659) in terms of tissue integration.

- Stability study was conducted, and the proposed device shelf life was demonstrated.

- Biocompatibility evaluation was performed and confirmed that Dextile™ Anatomical Mesh and its constitutive components

are compliant with ISO Standard 10993-1 for their intended patient contact profile.

- Usability tests were conducted and demonstrate that the subject Dextile™ Anatomical Mesh is acceptable for the intended users, uses and use environments.

This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Conclusion:
All testing demonstrates that the subject Dextile™ Anatomical Mesh is substantially equivalent to the predicate device, 3DMAX™ Light Mesh (K091659).