DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 20, 2015

C.R. Bard Incorporated
Ms. Mariya Buharin
Regulatory Affairs Specialist
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K142711
Trade/Device Name: ONFLEX™ Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: March 16, 2015
Received: March 17, 2015

Dear Ms. Buharin:

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" (21CFR 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,

Jennifer R. Stevenson -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)*
K142711

Device Name
ONFLEX™ Mesh

Indications for Use *(Describe)*
The ONFLEX™ Mesh is indicated for use in the reinforcement of soft tissue where weakness exists, such as in the repair of inguinal hernias.

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

This 510(k) Summary is provided per the requirements of section 21 CFR 807.92.

I. Submitter

Submitter's Name:	Davol, Inc., Subsidiary of C. R. Bard, Inc.
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Date prepared:	March 19th, 2015

II. Device

Trade Name:	ONFLEX™ Mesh
Common/Usual Name:	- Surgical Mesh
Classification Name:	- Mesh, Surgical, Polymeric (21 CFR § 878.3300)
Regulatory Class:	- Class II
Product Code:	-FTL

III. Predicate Devices

- Bard® 3DMax™ Light Mesh
  - K091659 (Davol, Inc.), FDA cleared on 08/08/2009
- Bard® Ventrio™ Hernia Patch,
  - K081777 (Davol, Inc.), FDA cleared on 09/29/2008
  - K100229 (Davol, Inc.), FDA cleared on 04/21/2010

No reference devices were used in this submission.

IV. Device Description

The proposed ONFLEX™ Mesh is a self-expanding, non-absorbable, sterile (Ethylene Oxide) prosthesis, made from monofilament polypropylene mesh and has a lightweight large pore design. This construction allows a prompt fibroblastic response through the interstices of the mesh as observed in a preclinical model, which may not correlate to performance in humans. The ONFLEX™ Mesh has an anatomical shape designed to cover potential defect areas. The ONFLEX™ Mesh also contains a pocket on the larger medial apex of the mesh to facilitate insertion and positioning of the device.

The proposed device contains SorbaFlex™ Memory Technology comprised of an absorbable PDO monofilament which forms an interrupted ring. SorbaFlex™ Memory Technology provides memory and stability to the device, facilitating ease of initial insertion and proper placement of the device. The PDO monofilament is folded and welded onto itself at the ends. The interrupted ring provides memory and stability to the device, facilitating ease of initial insertion and proper

placement of the device. The PDO monofilament fully degrades by means of hydrolysis *in vivo* in 6 – 8 months. The PDO monofilament is dyed violet by adding D & C Violet No. 2. The interrupted ring is placed within a mesh tube constructed from a knitted polypropylene monofilament. The purpose of the mesh tube is to contain the interrupted recoil ring during the degradation process. The interrupted ring, contained in the mesh tube, is sewn between two layers of mesh with polytetrafluoroethylene (PTFE) monofilament.

The ONFLEX™ Mesh has a blue limit line at the lateral portion of the mesh, composed of polypropylene monofilament dyed with Phthalocyaninato(2-) copper colorant, to provide visual feedback for where the device can be tailored. The ONFLEX™ Mesh can be tailored at the opening of the interrupted ring or outside of the blue limit line.

The ONFLEX™ Mesh is offered in two sizes: medium (0115410) and large (0115411). The proposed ONFLEX™ Mesh is considered a tissue contacting permanent implant according to Blue Book Memorandum issued on May 1, 1995, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing".

V. Indications for Use

The ONFLEX™ Mesh is indicated for use in the reinforcement of soft tissue where weakness exists, such as in the repair of inguinal hernias.

VI. Comparison of Technological Characteristics with the Predicate Devices

The ONFLEX™ Mesh has the same intended use and similar technological characteristics as the currently marketed predicates 3DMax™ Light Mesh (K091659) and Ventrio™ Hernia Patch (K081777/ K100229). The ONFLEX™ Mesh and predicates Ventrio™ Hernia Patch and 3DMax™ Light Mesh are intended for use in the reinforcement of soft tissue where weakness exists. The ONFLEX™ Mesh combines the large pore knit construction, anatomical shape, and blue marker features of 3DMax™ Light Mesh with the SorbaFlex™ Memory Technology, mesh tube and pocket features of Ventrio™ Hernia Patch.

The ONFLEX™ Mesh and the predicates, 3DMax™ Light Mesh and Ventrio™ Hernia Patch, are constructed from a polypropylene monofilament. The ONFLEX™ Mesh has a similar large pore knit construction, anatomical shape as the predicate 3DMax™ Light Mesh. The perimeter of the polypropylene mesh on the ONFLEX™ Mesh is heat sealed to form a smooth edge, similar to the predicate 3DMax™ Light Mesh. Additionally, both the proposed device and the predicate 3DMax™ Light Mesh use polypropylene monofilament dyed with Phthalocyaninato(2-) copper colorant to create a marker. 3DMax™ Light Mesh contains a stitched marker indicating the medial end of the device and the proposed ONFLEX™ Mesh contains a stitched blue limit line indicating the area of the mesh that may be tailored.

The ONFLEX™ Mesh utilizes a PDO monofilament ring mechanism similar to the Ventrio™ Hernia Patch. The ONFLEX™ Mesh's ring is interrupted and folded to form a loop on each end whereas the Ventrio Hernia™ Patch has an uninterrupted ring that is ultrasonically welded together. The ONFLEX™ Mesh uses the same mesh tube to encompass the ring mechanism as the predicate Ventrio™ Hernia Patch. This mesh tube is the same material composition, polypropylene, as the mesh that is used to construct the other mesh layers of the ONFLEX™ Mesh. The PDO monofilament in the mesh tube is sewn between two layers of mesh with PTFE monofilament in both the ONFLEX™ Mesh and the predicate Ventrio™ Hernia Patch. Both the ONFLEX™ Mesh and Ventrio™ Hernia Patch use an additional layer of mesh to form a pocket,

which facilitates insertion. However, the ONFLEX™ Mesh has one pocket on the larger medial apex of the mesh whereas the predicate Ventrio™ Hernia Patch has two pockets. Additionally, Ventrio™ Hernia Patch contains a layer of expanded polytetrafluoroethylene (ePTFE) which contacts bowel or viscera when used for soft tissue repair in ventral hernia, to minimize tissue attachment to the mesh. The proposed ONFLEX™ Mesh is designed to be used primarily in soft tissue repair in the inguinal canal, and thus does not contain such a design feature.

Mechanical testing was performed consistent with FDA Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh, issued March 2, 1999, to verify that the ONFLEX™ Mesh's performance characteristics are similar to that of the predicate devices.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination. Testing was performed in accordance per "FDA Guidance for the Preparation of Premarket Notification for a Surgical Mesh."

Biocompatibility Testing
Biocompatibility testing was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

ONFLEX™ Mesh is considered a tissue contacting permanent implant. Therefore, the following tests are required and were leveraged from the predicate devices in support of this premarket notification:

- Cytotoxicity
- Sensitization
- Intracutaneous reactivity
- Acute systemic toxicity
- Subchronic toxicity
- Genotoxicity
- Implantation

Electrical safety and electromagnetic compatibility (EMC)
There are no electrical or metal components in the ONFLEX™ Mesh; therefore the proposed device does not require EMC and Electrical Safety evaluation.

Software Verification and Validation Testing
The proposed ONFLEX™ Mesh does not contain software.

Mechanical Testing
The following physical and performance characteristics were measured to compare the proposed ONFLEX™ Mesh to the predicates 3DMax™ Light Mesh and Ventrio™ Hernia Patch:

- Mesh weave characteristics
- Mesh thickness
- Mesh pore size
- Mesh density
- Mesh stiffness

- Ball burst strength
- Suture pullout strength
- Tear strength
- PDO monofilament tensile strength
- Simulated deployment test

Animal Study
In vivo and *in vitro* resorption studies were performed to characterize the mechanical strength and resorption of the PDO monofilament in the SorbaFlex™ Memory Technology and were originally provided in support of the predicate Ventrio™ Hernia Patch via K081777. Since ONFLEX™ Mesh contains the same PDO monofilament as the predicate Ventrio™ Hernia Patch these resorption studies were adopted and provided in support of the ONFLEX™ Mesh.

Clinical Study
No clinical study was required in support of the ONFLEX™ Mesh.

VIII. Conclusions

The test results provided in this submission demonstrate that the ONFLEX™ Mesh is substantially equivalent to its predicates.