July 24, 2025

Davol Inc., Subsidiary of C. R. Bard, Inc.
Mohammed Ahmed
Regulatory Affairs Specialist
100 Crossings Blvd
Warwick, Rhode Island 02886

Re: K251955
Trade/Device Name: Onflex™ Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: June 23, 2025
Received: June 25, 2025

Dear Mohammed Ahmed:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TEK N. LAMICHHANE -S

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251955

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K251955

Submitter:

Davol Inc., Subsidiary of C.R. Bard, Inc.
100 Crossings Blvd.
Warwick, RI 02886
United States

Contact: Mohammed Z. Ahmed
Title: Regulatory Affairs Specialist
Email: Mohammed.Ahmed@bd.com
Phone: (401) 825-8509

Date of Submission: June 23, 2025

Subject Device:

Device Trade Name:	OnFlex™ Mesh
Common Name:	Surgical mesh
Classification Name:	Mesh, Surgical, Polymeric
Regulatory Class:	II
Regulation Number:	21 CFR 878.3300
Product Code:	FTL

Predicate Device:

Device Trade Name:	OnFlex™ Mesh (K142711), cleared on March 20, 2015
Common Name:	Surgical mesh
Classification Name:	Mesh, Surgical, Polymeric
Regulatory Class:	II
Regulation Number:	21 CFR 878.3300
Product Code:	FTL

Device Description:

The purpose of this Special 510(k) is to notify FDA of the changes to the OnFlex™ Mesh labeling. There are no changes to the device itself. The device description is identical to the device description for the predicate device, OnFlex™ Mesh (K142711), cleared on 20 March 2015.

The OnFlex™ Mesh is a self-expanding, non-absorbable, sterile device 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 design 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 OnFlex™ Mesh 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 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 OnFlex™ Mesh is considered a tissue contacting permanent implant.

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.

The subject and predicate devices have identical indications for use.

Technological Comparison to Predicate Device:

The subject device is identical to the predicate device in terms of design, materials, manufacturing, packaging, sterilization, biocompatibility, and shelf-life.

Device Characteristic	Subject Device: OnFlex™ Mesh (K251955)	Predicate Device: OnFlex™ Mesh (K142711)	Comparison Assessment
Device Classification	Class II Surgical Mesh 21 CFR 878.3300 Product Code: FTL	Class II Surgical Mesh 21 CFR 878.3300 Product Code: FTL	Same
Intended use	Soft tissue repair/reinforcement	Soft tissue repair/reinforcement	Same
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.	The OnFlex™ Mesh is indicated for use in the reinforcement of soft tissue where weakness exists, such as in the repair of inguinal hernias.	Same
Principles of Operation	• Insertion • Placement/Positioning	• Insertion • Placement/Positioning	Same
Materials	**Mesh**: Polypropylene monofilament **Interrupted Ring**: Polydioxanone (PDO) dyed with D & C Violet No.2 **Blue Limit Line:** Polypropylene monofilament dyed with Phthalocyaninato(2-) copper colorant **PTFE stitching:** Polytetrafluoroethylene (PTFE)	**Mesh**: Polypropylene monofilament **Interrupted Ring**: Polydioxanone (PDO) dyed with D & C Violet No.2 **Blue Limit Line:** Polypropylene monofilament dyed with Phthalocyaninato(2-) copper colorant **PTFE stitching:** Polytetrafluoroethylene (PTFE)	Same
Design	The OnFlex™ Mesh is a self- expanding, nonabsorbable, sterile device constructed of monofilament polypropylene mesh with a lightweight large pore design.	The OnFlex™ Mesh is a self- expanding, nonabsorbable, sterile device constructed of monofilament polypropylene mesh with a lightweight large pore design.	Same
Sizes	**Product Code** / **Size** / **Dimensions** 0115410 / Medium / 3.4” x 5.6”/8.6 cm x 14.2 cm 0115411 / Large / 4.0” x 6.2”/10.2 cm x 15.7 cm	**Product Code** / **Size** / **Dimensions** 0115410 / Medium / 3.4” x 5.6”/8.6 cm x 14.2 cm 0115411 / Large / 4.0” x 6.2”/10.2 cm x 15.7 cm	Same

Device Characteristic	Subject Device: OnFlex™ Mesh (K251955)	Predicate Device: OnFlex™ Mesh (K142711)	Comparison Assessment
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same

The purpose of this Special 510(k) is to notify FDA of labeling updates to the OnFlex™ Mesh that are being made to comply with the requirements of the European medical device regulation, Regulation (EU) 2017/745, as well as to align the labeling with other hernia mesh devices across the Davol Inc. portfolio. These labeling modifications do not impact the substantial equivalence between the subject and predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions:

No non-clinical or clinical testing was provided in support of this Special 510(k).

Conclusion:

The subject device and predicate device have the same indications for use and technological characteristics. The only differences between the subject and predicate device are modifications to the labeling for the subject device. These labeling modifications do not impact the safety or effectiveness of the subject device, nor do they impact the substantial equivalency between the subject and predicate devices. Additional changes taken under documentation to file since the clearance of K142711 were also found to have no impact to the substantial equivalence of the subject device. Therefore, the subject device, OnFlex™ Mesh, is substantially equivalent to the predicate device, OnFlex™ Mesh (K142711).