July 17, 2020

C.R. Bard, Inc.
Shannon Green
Sr. Regulatory Affairs Specialist
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K200818
Trade/Device Name: 3DMax MID Anatomical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: March 27, 2020
Received: March 30, 2020

Dear Shannon Green:

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 and Part 809); 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,

Cindy Chowdhury, Ph.D., M.B.A.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200818

Device Name
3DMax™ MID Anatomical Mesh

Indications for Use *(Describe)*
The 3DMax™ MID Anatomical Mesh is indicated for use in the reinforcement of soft tissue, where weakness exists, 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
K200818

Submitter Information:

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Contact Person: Shannon Green
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Date of Submission: March 27, 2020

Subject Device Name:

Name of Device:	3DMax™ MID Anatomical Mesh
Common or Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical, Polymeric
Regulatory Class:	Class II
Regulation Number:	21 CFR 878.3300
Product Code:	FTL

Primary Predicate Device:

Name of Device:	3DMax™ Light (K091659), cleared on August 3, 2009
Common or Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical, Polymeric
Regulatory Class:	Class II
Regulation Number:	21 CFR 878.3300
Product Code:	FTL

Secondary Predicate Device:

Name of Device:	VITAMESH™ MacroPorous PP Mesh (K172636), cleared on April 30, 2018
Common or Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical, Polymeric
Regulatory Class:	Class II

Regulation Number:	21 CFR 878.3300
Product Code:	FTL

Device Description:

3DMax™ MID Anatomical Mesh is a sterile, single-use device for prescription use only. It is made from the identical macroporous polypropylene mesh as the secondary predicate device (VITAMESH™ MacroPorous PP Surgical Mesh, K172636) monofilament polypropylene and has an open pore design with a 3-dimensional curve and preformed, semi-rigid edges based on the design of the primary predicate 3DMax™ Light (K091659). The orientation markings help to determine the orientation and position of the 3DMax™ MID Anatomical Mesh with regards to groin anatomy. The subject device has the identical intended use as the primary and predicate devices; soft tissue repair/reinforcement.

Indications for Use of Device:

The 3DMax™ MID Anatomical Mesh is indicated for use in the reinforcement of soft tissue, where weakness exists, in the repair of inguinal hernias.

Technological Comparison to Predicate Devices:

The subject device, 3DMax™ MID Anatomical Mesh, has the following similarities to the predicate devices:

- The intended use of the subject device, i.e. for the repair/reinforcement of inguinal hernias, is identical to 3DMax™ Light Mesh (K091659) and to VITAMESH™ MacroPorous PP Surgical Mesh (K172636).
- The indication for use of the subject device is identical to the primary predicate device, 3DMax™ Light Mesh (K091659).
- The mesh design is similar to 3DMax™ Light Mesh (K091659).
- The mesh sizes are within a similar range of 3DMax™ Light Mesh (K091659).
- The principle of operation for inguinal hernia repair is similar to 3DMax™ Light Mesh (K091659) and VITAMESH™ MacroPorous PP Mesh (K172636).
- The polypropylene material is identical to the macroporous polypropylene mesh as VITAMESH™ MacroPorous PP Surgical Mesh (K172636).
- The blue colorant (dye) used in the medial marker is identical to that used in the polypropylene monofilament of 3DMax™ Light Mesh (K091659).

- The sterilization method (ethylene oxide) is identical to 3DMax™ Light Mesh (K091659) and VITAMESH™ MacroPorous PP Mesh (K172636).

The subject device, 3DMax™ MID Anatomical Mesh, incorporates the following changes as compared to the predicate devices:

- The floating stitches are constructed of a larger diameter polypropylene monofilament (7.5mil) in the subject device as compared to the predicate 3DMax™ Light (K091659) (4.8mil).
- The orientation markings of the subject device include additional vertical and horizontal blue polypropylene monofilament lines to assist with alignment of mesh along the inguinal ligament and spermatic cord structure.

3DMax™ MID Anatomical Mesh has the identical intended use as both the primary and secondary predicate devices. The subject device has the identical indications for use as the primary predicate device and similar indications for use as the secondary predicate device. The subject device is manufactured from material identical to the secondary predicate device and incorporates the identical blue dye colorant as the primary predicate device. 3DMax™ MID Anatomical Mesh has identical packaging materials as the primary predicate device. The subject device has the identical sterilization method (ethylene oxide) as compared to the predicate devices and similar principle of operation and manufacturing processes as compared to the predicate devices. Any differences in the technological characteristics were thoroughly tested and the results demonstrate that there are no new questions of safety and effectiveness.

Performance Data:

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

1. **Biocompatibility Testing:**

   The biocompatibility evaluation for the 3DMax™ MID Anatomical Mesh was conducted in accordance with the Guidance for Industry and Food and Drug Administration Staff Use of International Standard ISO 10993-1, "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*" June 16, 2016, and

International Standard ISO 10993-1 "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*," as recognized by the FDA.

The subject device mesh materials are identical to the mesh materials utilized in the successful clearance of the secondary predicate VITAMESH™ MacroPorous PP Surgical Mesh (K172636), and therefore considered safe and biocompatible. Utilizing the Biocompatibility Evaluation Flow Chart, Attachment D of the Guidance for Industry and Food and Drug Administration Staff Use of International Standard ISO 10993-1, "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*" (June 16, 2016), it has been concluded that all biocompatibility requirements are met. Thus, the tests specific to the polypropylene material of 3DMax™ MID Anatomical Mesh were not repeated. However, in order to address any risks associated with interaction of the materials of the subject device mesh and the packaging materials (identical to the primary predicate 3DMax™ Light Mesh, K091659), cytotoxicity testing was completed. Refer to **Table 1**.

Table 1: Biocompatibility Testing of 3DMax™ MID Anatomical Mesh

Test Method	**Results**
MEM Cell Cytotoxicity Elution	Pass

The biocompatibility test results demonstrate that the subject device is biocompatible and there are no interactions between the subject device and the packaging materials to affect the previously established safety and effectiveness. Therefore, the subject device is safe and is biocompatible for its intended use.

2. Product Testing:

The performance test results demonstrate that the subject device successfully met the established acceptance criteria and is substantially equivalent to the 3DMax™ Light Mesh (K091659) and the VITAMESH™ MacroPorous PP Surgical Mesh (K172636). Completed performance testing on the subject device is listed in **Table 2**.

Table 2: Performance Testing - Bench

Performance Test (Bench)	**Test Method**
Substantial Equivalency Testing	- Mesh Thickness

	- Mesh Density - Mesh Knit Construction - Pore Size - Stiffness - Tensile/Break Strength (Machine and Cross directions) - Percent Elongation at Break (Machine and Cross directions) - Suture Pullout (Machine and Cross directions) - Burst Strength - Tear Resistance (Cross and Machine direction) - Trocar Deployment Force (Insertion)
Design Validation Usability Testing	Attributes: - IFU, Packaging, Labeling - Deployment - Positioning and Placement - Fixation - Inguinal Hernia Repair

3. Animal Studies:

A 2-week GLP study in a rabbit model was performed on the original polypropylene mesh utilized in VITAMESH™ MacroPorous PP Surgical Mesh as compared to its original predicate, Bard™ Mesh in order to conduct a histological evaluation of the host inflammatory/fibrotic response. As the current VITAMESH™ MacroPorous PP Mesh (K172636) is manufactured with a polypropylene resin which is chemically, and thus toxicologically equivalent to the original polypropylene resin, additional testing was not conducted.

4. Clinical Study:

Review of Guidance for Industry *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)],* cited in Section 12, it was determined that a clinical study report is not required in determining the safety and effectiveness of

the subject device, 3DMax™ MID Anatomical Mesh, as there are no modified indications for use, and no significant technological differences and/or non-clinical testing methods, when compared to the primary and secondary predicate devices.

NOTE:

Fixation may not be necessary.

Depending on the size of the defect, surgical technique used, the quality of the anatomical structures and tissue integrity, fixation may not be necessary. The mesh should be sized with appropriate overlap for the size and location of the defect, allowing for complete coverage of a fully dissected myopectineal orifice. The operating surgeon should consider the surgical technique when making decisions regarding the risk and benefit of fixation or non-fixation. Any additional clinical factors applicable to the patient should be considered.

According to International Hernia Guidelines for Groin Hernia Management[1], "The systematic review and meta-analyses—all judged to be of moderate quality per GRADE guidelines—revealed no significant differences in the rates of recurrence or postoperative pain between permanent tack fixation and non-fixation in either TEP or TAPP." Additionally, the International Guidelines states, "In TEP and TAPP inguinal/femoral hernia repair, nonfixation of mesh is recommended in almost all hernia types except large medial defects (M3 EHS classification) where mesh fixation is recommended." The majority of the studies reviewed and referenced in the International Hernia Guidelines for Groin hernia management clearly described limitations of their studies calling for large randomized control, multicenter studies, adequately powered with long term follow up. Example of the limitations listed include:

1. No routine imaging at the study completion to rule out folding or bunching of the mesh. Such an event is unlikely to cause recurrent hernia because of the wide margin of overlap but may cause chronic pain, stiffness, compliance issues and ultimately adhesion formation and visceral erosion. These adverse events would require much longer follow up than was achieved in the studies referenced.
2. The studies tended to be under powered without clear definition of primary end point.
3. There was a high probability of bias in the studies because a number of them were unevenly matched, lacking detail of hernia size, hernia type, type of mesh used,

and were reported from a single center or single surgical group. These studies frequently lacked, an intent to treat analysis, uniform method of randomization and blinding of investigators. They were retrospective in nature or were meta analyses which were difficult to interpret because of different definitions pain and hernia recurrence. Many of the RCTs had a follow up of less than 2 years.

[1]Hernia Surge Group. International guidelines for groin hernia management. Hernia. 2018;22(1):1-165.

Conclusion:

3DMax™ MID Anatomical Mesh has the identical intended use, indications for use, packaging materials and sterilization method as the primary predicate device. The subject and secondary predicate device have identical intended use, materials of construction and sterilization method. Furthermore, the subject device has similar mesh technological characteristics, principle of operation, and manufacturing processes as the primary and secondary predicate devices. Any differences in the technological characteristics between the subject device and the predicate devices were thoroughly assessed and evaluated. All test results support that the subject device's safety, effectiveness and performance are similar to the predicate devices. Therefore, 3DMax™ MID Anatomical Mesh is substantially equivalent to 3DMax™ Light (K091659) and VITAMESH™ MacroPorous PP Surgical Mesh (K172636).