October 31, 2018

FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft
% Neil Armstrong
RA Advisor to FEG Textiltechnik
MeddiQuest Regulatory Affairs Ltd
Unit 73B Hebron Industrial Estate
Kilkenny, R95 CRK2
Ireland

Re: K182087
Trade/Device Name: DynaMesh-POSTERIOR
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: July 11, 2018
Received: August 2, 2018

Dear Mr. Armstrong:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph Nielsen -S

Digitally signed by Joseph Nielsen -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Joseph Nielsen -S, 0.9.2342.19200300.100.1.1=2000367505
Date: 2018.10.31 08:07:30 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182087

Device Name
DynaMesh®- POSTERIOR

Indications for Use *(Describe)*
DynaMesh®- POSTERIOR serves to support the tissue and stabilize the fascial structures of the abdominal wall.
DynaMesh®- POSTERIOR is indicated for repairing hernias in all current extraperitoneal surgical techniques.

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

(as required by 21 CFR 807.92(c))

Owner's Name:

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Date this Summary was Prepared: July 11, 2018

Classification:

Name:	Mesh, Surgical, Polymeric
Regulation:	21 CFR 878.3300
Product Code:	79 FTL
Regulatory Class:	II

Common/Usual Name:

Mesh Implant used in Hernia Surgery

Proprietary Name:

DynaMesh®-POSTERIOR

Predicate Devices used to Demonstrate Substantial Equivalence:
The FEG Textiltechnik DynaMesh®-POSTERIOR is substantially equivalent to:

Product Name:	DynaMesh®-VENTRAL, K161550
Manufacturer:	FEG Textiltechnik, Aachen, Germany

Description, including Intended Use
DynaMesh®- POSTERIOR serves to support the tissue and stabilize the fascial structures of the abdominal wall.
DynaMesh®- POSTERIOR is indicated for repairing hernias in all current extraperitoneal surgical techniques.

The FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH DynaMesh®-POSTERIOR is a textile structure knitted from non-absorbable, bio-stable Polyvinylidene fluoride (PVDF) monofilament fiber.

The grade of Polyvinylidene Fluoride (PVDF) used is SOLEF®1008 from Solvay Solexis.

The knitted mesh structure consists of uncoloured PVDF Monofilaments with a zig-zag pattern of green-coloured PVDF Monofilaments as visual aid to the clinician that facilitates a rapid orientation and visual monitoring of whether the mesh is positioned tension-free.

The used green dye is Phtalocyanine green, CAS1328-53-6, PG7 from BASF.

DynaMesh®-POSTERIOR is supplied as a sterile, flexible, flat sheet of material without any coatings. The FEG Textiltechnik's DynaMesh®-POSTERIOR will be packed in a cardboard box. Within the cardboard box the device will be double-packed in two paper-poly pouches suitable for Ethylene Oxide sterilization; the labeled outer pouch contains the inner pouch and four adhesive labels for use on patient records.

Technological Characteristics Compared to Predicate Devices
The FEG Textiltechnik DynaMesh®-POSTERIOR is:

- for the same intended use,
- knitted with the same equipment by the same personnel in the same facilities,
- packaged in same materials by same processes in the same facilities
- labeled with the same label format by the same processes in the same facilities
- contract sterilized in the same chamber with the same cycle at the same subcontract facility

as the FEG Textiltechnik DynaMesh®-VENTRAL K161550.

The FEG Textiltechnik DynaMesh®-POSTERIOR has a slightly different structure to give more uniform properties in both horizontal and vertical directions, as a clinician

preference option for situations where there is no clear preferred orientation.

Feature	FEG Textiltechnik DynaMesh®-POSTERIOR	FEG Textiltechnik DynaMesh®-VENTRAL
Clearance/Approval	Subject Device	K161550
Structure	knitted mesh	same
Material	100% PVDF Monofilament	same
Manufacturing Process	Knitted by FEG	same
Packaging Materials	poly, paper, cardboard	same
Packaging Process	Packed by FEG	same
Sterilization Process	Sterilized by Rose GmbH	same

Summary of Non-Clinical and Clinical Data

Various Laboratory Bench Tests have been conducted on DynaMesh®-POSTERIOR to demonstrate performance to an accepted norm and/or substantial equivalence to the predicate products:

- Burst Strength Test
- Tensile Strength
- Maximum elongation
- Suture Pullout Strength Test
- Tear Resistance Testing
- Porosity Test
- Mesh stiffness

Conclusion

From review of the non-clinical and clinical data, FEG Textiltechnik conclude that the DynaMesh®-POSTERIOR is substantially equivalent in terms of safety, effectiveness and performance to the predicate device.