Revised Section 5 of K131530 "510(k) Summary" September 14, 2012

DynaMesh®
by FEG Textiltechnik mbH
www.dyna-mesh.com

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510(k) Summary
(as required by 21 CFR 807.92(c))

Owner's Name:

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OCT 2 3 2013

Date this Summary was Prepared:
September 14, 2013

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®-CICAT

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

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Product Name: DynaMesh®-PP (Light and Standard), K073579
Manufacturer: FEG Textiltechnik, Aachen, Germany

Description, including Intended Use
The FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH DynaMesh®-CICAT is intended for hernia surgery for reinforcing connective tissue structures. DynaMesh®-CICAT serves to support the tissue and stabilize the fascial structures of the abdominal wall. DynaMesh®-CICAT is constructed for repairing incisional hernias in all current extraperitoneal surgical techniques.
The FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH DynaMesh®-CICAT is a textile structure knitted from non absorbable, bio□ stable Polyvinylidene fluoride (PVDF) monofilament fiber.
Polyvinylidene Fluoride (PVDF) has been used for approximately 20 years for long-term implants in cardiac and vascular surgery because of its biocompatibility and durability. PVDF is a high performance polymer material with very high material purity.

The grade of Polyvinylidene Fluoride (PVDF) used is SOLEF®1008 of Solvay Solexis.
Product information:
Trade Name: PVDF SOLEF® 1008/0001
Chemical Name: Polyvinylidene Fluoride
CAS Reg. No.: 24937-79-9

The knitted mesh structure consists of uncoloured PVDF Monofilaments with a pattern of zig-zag marking stripes as visual aid to the clinician facilitating correct mesh positioning; the mesh is correctly positioned when the zig-zag□ stripes are in the craniocaudal direction.

DynaMesh®-CICAT is supplied as a sterile, flexible, flat sheet of material without any coatings or additives. The FEG Textiltechnik's DynaMesh®-CICAT 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®-CICAT 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®-PP (Light and Standard) K073579.

Clearance/Approval	Subject Device	K073579
Structure	knitted mesh	same
Material	100% PVDF Monofilament	Polypropylene
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®-CICAT to demonstrate performance to an accepted norm and/or substantial equivalence to the predicate products:

- Burst Strength Test
- Tensile Testing
- Tri-Elasticity Testing
- Suture Pullout Strength Test
- Tear Resistance Testing
- Porosity Test

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

FEG Textiltechnik Forschungs- und Entwicklungsgellschaft mbH
C/O Mr. Neil R. Armstrong
MeddiQuest Limited
Herlington House, Orton Malborne
Peterborough, Cambridgeshire PE2 5XS
United Kingdom

October 23, 2013

Re: K131530
Trade/Device Name: Dynamesh - CICAT
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: September 14, 2013
Received: September 23, 2013

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. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131530

Device Name: DynaMesh®-CICAT

Indications for Use:

DynaMesh®-CICAT serves to support the tissue and stabilize the fascial structures of the abdominal wall.
DynaMesh®-CICAT is indicated for repairing incisional hernias in all current extraperitoneal surgical techniques.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED).

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131530