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August 3, 2008
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510(k) Summary

AUG 18 2008

FEG Textiltechnik
Forschungs- und Entwicklungsgesellschaft mbH
Juelicher Strasse 338a
D-52070 Aachen
Germany
Telephone: 011 49 241 189 2374-0
Fax: 011 49 241 189 2374-59

Owner's Name

FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH
Juelicher Str. 338a
D - 52070 Aachen
Germany
Tel.: 011 49 241 189 2374-0
Fax: 011 49 241 189 2374-59

Contact Person: Stefan Schneemelcher
e-mail: schneeme@feg-textiltechnik.de

Date this Summary was Prepared:

August 01, 2008

Classification:

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

Common/Usual Name:

Hernia Repair Polypropylene Mesh

Proprietary Name:

DynaMesh-PP (Standard and Light)

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Establishment Registration Number:

The device will be manufactured by:

FEG Textiltechnik
Forschungs- und Entwicklungsgesellschaft mbH
Juelicher Strasse 338a
D-52070 Aachen
Germany
Establishment Registration Number: "to be applied for"

"knitted" by

Julius Boos jr. GmbH & Co. KG
Liegnitzer Strasse 16
D-42277 Wuppertal
Germany
Establishment Registration Number: none

and sterilized by:

Rose GmbH
Gottbillstrasse 25-30
D-54294 Trier
Germany
Establishment Registration Number: none

Substantial Equivalence:

The FEG Textiltechnik DynaMesh-PP is substantially equivalent in design, use and materials to the:

Sofradim Production Pariente Polypropylene Mesh – K991400
GFE Medizintechnik GmbH TiMESH, TiMESH-TC - K031225
Aesculap Inc Optilene Mesh - K061704
Davol/Bard (Usher's) Marlex (various) - K792281, K922916
Atrium Medical Corp Meshes (various) - K930669, K002093, K070192

The FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH DynaMesh-PP is made of the same basic material as the Sofradim Production Pariente Polypropylene Mesh – K991400, polypropylene.

The FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH DynaMesh-PP is manufactured by similar processes to the Sofradim Production Pariente Polypropylene Mesh – K991400.

The FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH DynaMesh-PP is sterilized by a conventional sterilization cycle as is the Sofradim Production Pariente Polypropylene Mesh – K991400.

The FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH DynaMesh-PP has a reduced effective surface mesh area and weight per unit area compared to the Sofradim Production Pariente Polypropylene Mesh – K991400.

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The FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH DynaMesh-PP is also substantially equivalent in terms of materials, construction, processing and intended use to the other predicate products:

GFE Medizintechnik GmbH TiMESH, TiMESH-TC - K031225
Aesculap Inc Optilene Mesh - K061704
Davol/Bard (Usher's) Marlex (various) - K792281, K922916
Atrium Medical Corp Meshes (various) - K930669, K002093, K070192

Description of Product:
The FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH DynaMesh-PP is a polypropylene mesh, knitted from non absorbable, bio-stable, polypropylene monofilament fiber. DynaMesh-PP is supplied as a sterile, flexible, flat sheet of material.
DynaMesh-PP is intended for use during hernia surgery, where the flat sheet can be cut to size, based on patient specific anatomical requirements.
FEG Textiltechnik's DynaMesh-PP will be available in two mesh densities, standard and light, and a variety of sizes
The FEG Textiltechnik DynaMesh-PP will be packaged double-packed in two transparent plastic bags:
- the inner transparent bag contains the device only
- the outer transparent bag contains the inner bag and four adhesive labels for patient records.
The product label will be on the outer bag, which is then protected by a cardboard box.
The product has a stated shelf-life of 3 years which is supported by real-time testing.

Intended use:
DynaMesh-PP is a polypropylene mesh intended to support tissue and stabilize fascial structures of the abdominal wall.
DynaMesh-PP is indicated for repairing hernias, parietal reinforcement of tissues and abdominal wall repair.

Technological Comparison to Predicate Device

Feature	**Unit**	**Subject Device** FEG Textiltechnik DynaMesh-PP This 510(k) Submission		**Predicate Device** Sofradim Parietene Mesh K991400	
		Standard	Light	Standard	Light
material		polypropylene	same	same	same
mesh form		knitted	same	same	same
sizes		various sizes supplied to be cut to suit patient	same	same	same
supplied sterile		conventional sterilization method	same	same	same
weight	$g\ m^{-2}$	72	36	76	36
yarn diameter	µm	165	140	150	115
yarn length per unit	$m\ m^{-2}$	3579	2519	4388	3537

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Feature	Unit	Subject Device FEG Textiltechnik DynaMesh-PP This 510(k) Submission		Predicate Device Sofradim Parietene Mesh K991400	
		Standard	Light	Standard	Light
area of mesh patch					
surface area per unit area of mesh patch	$m^2 m^{-2}$	1.86	1.11	2.07	1.28
tensile strength - longitudinal	$N cm^{-1}$	52	28	42	23
tensile strength - transverse	$N cm^{-1}$	59	22	44	19
suture pull-out strength - longitudinal	$N cm^{-1}$	47	30	43	31
suture pull-out strength - transverse	$N cm^{-1}$	43	32	50	19

Conclusion
Based on the above information, FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH believes that DynaMesh-PP (standard and light) can be determined substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 2008

FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH
% MeddiQuest Limited
Mr. Neil R. Armstrong
Business & Technology Center/Bessemer Drive
Stevenage, Hertsfordshire
SG2 2DX
United Kingdom

Re: K073579
Trade/Device Name: DynaMesh-PP (Standard and Light)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: August 3, 2008
Received: August 11, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Attachment 1

Indications for Use

510(k) Number (if known): _____
Device Name: _ DynaMesh-PP (Standard and Light)___

Indications for Use:

DynaMesh-PP is a polypropylene mesh intended to support tissue and stabilize fascial structures of the abdominal wall.
DynaMesh-PP is indicated for repairing hernias, parietal reinforcement of tissues and abdominal wall repair.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073579