



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 27, 2015

Atrium Medical Corporation
Mr. Timothy J. Talcott
Senior Director of Regulatory Affairs
5 Wentworth Drive
Hudson, New Hampshire 03051

Re: K151437

Trade/Device Name: ProLite™ Mesh, ProLite Ultra™ Mesh, and ProLoop™ Mesh Plug
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: May 28, 2015
Received: May 29, 2015

Dear Mr. Talcott:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

David Krause -S

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

2 Indications For Use Statement

510(k) Number (if known): K151437

Device Name: ProLite™ Mesh, ProLite Ultra™ Mesh, and ProLoop™ Mesh Plug

Indications for Use: ProLite Mesh and ProLite Ultra Mesh are intended for use in soft tissue deficiencies including hernia repair, traumatic or surgical wounds, and chest wall reconstruction procedures requiring reinforcement with a non-absorbable supportive material.

ProLoop Mesh Plug is intended for use in soft tissue deficiencies including hernia repair and traumatic or surgical wounds requiring reinforcement with a non-absorbable supportive material.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter-Use _____
(Part 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)

1 510(K) Summary

Submission Date: May 28, 2105

1.1 Submitter Information:

Submitted by: Atrium Medical Corporation
5 Wentworth Drive
Hudson, NH 03051

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1.2 Device Information

Trade/Proprietary Name: ProLite and ProLite Ultra Mesh, and ProLoop Mesh Plug

Common/Usual Name: Mesh, Surgical, Polymeric

Regulation Name: Surgical Mesh

Device Class: 21 CFR 878.3300, Class II

Product Code: FTL

Reviewing Panel: General & Plastic Surgery

Predicate Devices:

K930669	Atrium ProLite™ Mesh
K002093	Atrium ProLite Ultra™ Mesh
K930669	Atrium ProLoop™ Mesh Plug

- Device Description:** ProLite™ and ProLite Ultra™ Mesh are sterile, non-absorbable, knitted polypropylene monofilament mesh material. The ProLoop™ Mesh Plug is a non-absorbable, lightweight, pre-formed, three-dimensional plug constructed of knitted rows of monofilament polypropylene with multiple protruding monofilament loops. The devices are available in various configurations with sizes up to 12" X 18". The devices are terminally sterilized using Ethylene Oxide and intended as a single use device.
- Indications for Use:** ProLite Mesh and ProLite Ultra Mesh are intended for use in soft tissue deficiencies including hernia repair, traumatic or surgical wounds, and chest wall reconstruction procedures requiring reinforcement with a non-absorbable supportive material.
- ProLoop Mesh Plug is intended for use in soft tissue deficiencies including hernia repair and traumatic or surgical wounds requiring reinforcement with a non-absorbable supportive material.
- Technological Characteristics** This submission does not contain technological changes for subject devices. ProLite, ProLite Ultra and ProLoop have the same technological characteristics as previously cleared ProLite Family devices (K930669 and K002093). The subject devices differ only from the predicate devices in the indications for use and contraindications in the labeling.
- There are no new types of questions of safety and effectiveness raised by these differences, thereby supporting substantial equivalence to predicates.
- Performance Characteristics** The mesh materials used to construct the Atrium ProLite, ProLite Ultra and ProLoop Mesh have not been modified and remain the same as those described in predicate polypropylene mesh devices.
- Conclusion:** This notification contains all information required by 21 CFR 807.87. Atrium believes the labeling changes allow the devices to remain substantially equivalent to each other and do not raise any new types of safety or effectiveness questions.