K100076

K.

510K-Summary

For

Atrium C-Qur™ Device Modification

JAN 26 2010

1. SPONSOR

Name and Address

ATRIUM MEDICAL CORP.
5 Wentworth Dr.
Hudson, NH 03051, USA

Establishment Registration Number

1219977

2. DEVICE NAME

Proprietary Name:	Atrium C-Qur™ OVT Mesh
Common/Usual Name:	Surgical Mesh
Classification Name:	Mesh, surgical, polymeric

3. DEVICE CLASS

Regulation Number:	21 CFR 878.3300
Regulation Name:	Surgical mesh
Regulatory Class:	II
Product Code	FTL

4. PREDICATE DEVICES

Product Name	*Filing #*	*Concurrence Date*
Atrium C-Qur™ Surgical Mesh	K050311	03/31/2006

5. DEVICE DESCRIPTION

The Atrium C-Qur™ OVT Mesh is a surgical mesh used during surgical procedures. The mesh contains two layers of mesh stitched together. The second layer is cut into flaps. The intent of the addition of a second layer with flaps is to allow the surgeon to more easily position and attach the mesh to the surgical site.

6. INTENDED USE

The Atrium C-Qur™ OVT Mesh is indicated for use in hernia repair, chest wall reconstruction, traumatic or surgical wounds and other fascial surgical intervention procedures requiring reinforcement with a non-absorbable supportive material.

7. TECHNOLOGICAL CHARACTERISTICS

C-Qur™ OVT Mesh's intended use and its material composition are identical to that of its predicate device and it is therefore substantially equivalent to its legally marketed predicate devices.

8. PERFORMANCE DATA

Results of verification testing indicate that the product meets the established performance requirements.

9. CONCLUSION

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the modified device is substantially equivalent to the Predicate Devices under the Federal Food, Drug, and Cosmetic Act.

Contact Person

Jacqueline E.M. Emery, BS Engineering

Sr. Regulatory Affairs Specialist
Telephone: 603-880-1433 X5366

Email: jemery@atriummed.com

Date

January 8, 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

JAN 26 2010

Atrium Medical Corporation
% Ms. Jacqueline E.M. Emery
Senior Regulatory Affairs Specialist
5 Wentworth Drive
Hudson, New Hampshire 03051

Re: K100076
Trade/Device Name: Atrium C-Qur™ OVT Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: January 08, 2010
Received: January 21, 2010

Dear Ms. Emery:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

J. Statement of Indications for Use

Indications for Use Statement

510(k) Number (if known)	To be Assigned
Device Name	Atrium C-Qur™ OVT Mesh
Indications for Use	The Atrium C-Qur™ OVT Mesh is indicated for use in hernia repair, chest wall reconstruction, traumatic or surgical wounds and other fascial surgical intervention procedures requiring reinforcement with a non-absorbable supportive material

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100076