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

October 22, 2015

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

Re: K151386
Trade/Device Name: C-QUR, C-QUR FX, C-QUR TacShield, C-QUR V-Patch, C-QUR CentriFX, C-QUR Mosaic
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: September 21, 2015
Received: September 22, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K15386

Device Name

C-QUR Mesh

Indications for Use *(Describe)*

C-QUR Mesh is 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151386

Device Name

C-QUR FX Mesh

Indications for Use *(Describe)*

C-QUR FX Mesh is 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.

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)

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See PRA Statement below.

510(k) Number *(if known)*
K151386

Device Name

C-QUR V-Patch Mesh

Indications for Use *(Describe)*

C-QUR V-Patch Mesh is 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.

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)

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510(k) Number *(if known)*
K151386

Device Name

C-QUR TacShield Mesh

Indications for Use *(Describe)*

C-QUR TacShield Mesh is 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.

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)

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See PRA Statement below.

510(k) Number *(if known)*
K151386

Device Name

C-QUR CentriFX Mesh

Indications for Use *(Describe)*
C-QUR CentriFX Mesh is 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.

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)

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Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151386

Device Name

C-QUR Mosaic Mesh

Indications for Use *(Describe)*
C-QUR Mosaic Mesh is 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.

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)

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1 510(K) Summary

Submission Date: May 20, 2105

1.1 *Submitter Information:*

Submitted by:	Atrium Medical Corporation 5 Wentworth Drive Hudson, NH 03051
Contact Person:	Timothy J. Talcott Senior Director of Regulatory Affairs Phone: (443) 283-2768 Email: timothy.talcott@maquet.com Phone: (603) 880-1433 x 5342 Fax: (603) 821-1420

1.1 *Device Information*

Trade/Proprietary Name	C-QUR Mesh, C-QUR FX Mesh, C-Qur V-Patch Mesh, C-QUR TacShield Mesh, C-QUR CentriFX Mesh, and C-QUR Mosaic Mesh
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:	K050311	Atrium C-QUR™ Mesh
	K082748	Atrium C-QUR™ FX Mesh
	K090909	Atrium C-QUR V-Patch™ Mesh
	K100076	Atrium C-QUR TacShield™ Mesh
	K110110	Atrium C-QUR CentriFX™ Mesh
	K121070	Atrium C-QUR Mosaic™ Mesh

Device Description: C-QUR™ Mesh is a sterile, knitted polypropylene monofilament mesh material for tissue reinforcement with a bio-absorbable, animal derived oil coating (O3FA) composed of fatty acids, lipids and glycerides. The C-QUR Mesh family is 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: C-QUR Mesh is 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.

Technological Characteristics

This submission does not contain technological changes for subject devices. C-QUR Mesh has the same technological characteristics as previously cleared C-QUR Mesh devices (K050311, K082748, K090909, K100076, K110110 and K121070).

The subject devices differ only from the predicate devices in the indications for use, contraindications, and MR compatibility 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 C-Qur™ Mesh have not been modified and remain the same as those described in predicate C-QUR Mesh devices.

Conclusion: This notification contains all information required by 21 CFR 807.87. Atrium believes the labeling changes allow the devices to be remain substantially equivalent to each other and do not raise any new types of safety or effectiveness questions.