

510(k) Summary

NOV 20 2012

**Date Prepared:** October 24, 2012  
**Company:** Angiotech  
 100 Dennis Dr.  
 Reading, PA 19606  
**Contact:** Kirsten Stowell  
 Regulatory Affairs Manager  
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**Device trade name:** Quill™ Monoderm Knotless-Tissue Closure Device, Variable Loop Design

**Device Common Name:** Absorbable poly(glycolide/l-lactide) Surgical Suture

**Device classification:** Absorbable poly(glycolide/l-lactide) Surgical Suture  
 Product code, GAM  
 21 CFR 878.4493  
 Class II

**Legally marketed devices to which the device is substantially equivalent:**

K122898	Quill™ Monoderm™ Knotless Tissue-Closure Device, Variable Loop Design, Size 2-0
K113744:	Quill™ PDO Knotless Tissue-Closure Device (Polydioxanone)
K072028:	Quill™ Self-Retaining System (SRS) comprised of Monoderm™

**Description of the device:** The Quill™ Monoderm™ Knotless Tissue-Closure Device, Variable Loop Design is a sterile, synthetic absorbable tissue-closure device that is intended for use in the closure of soft tissue. It is comprised of a copolymer of glycolide and e-caprolactone, undyed, or dyed with D&C Violet No. 2. The device is designed with small uni-directional barbs along the long axis of the suture monofilament which contains a welded primary loop and secondary loop design at the distal end. It is available in diameter Sizes 2-0 to 0 in various lengths affixed to various needle types.

**Indications for Use:** Quill™ Knotless Tissue-Closure Device comprised of Monoderm™ is indicated for soft tissue approximation where use of an absorbable suture is appropriate.

**Substantial Equivalence:** The Quill™ Monoderm™ Knotless Tissue-Closure device, Variable Loop Design is identical in material composition and size range as the Quill™ Monoderm™ predicates. The proposed device is identical in design to the Quill™ Monoderm™ Knotless Tissue-Closure Device and Quill™ PDO Knotless Tissue-Closure Device predicate devices. In addition, the proposed device has the same intended use as all three predicate devices.

**Performance tests:** Non-clinical laboratory performance testing was conducted to confirm that the Quill™ Monoderm™ Knotless Tissue-Closure device, Variable Loop Design, conforms to the USP monograph for absorbable sutures for tensile strength (as applicable) and needle attachment. This testing was performed in accordance with FDA's Class II Special Controls Guidance Document: Surgical Sutures, Issued June 3, 2003. Additional performance testing was conducted in order to demonstrate substantial equivalence to the predicate devices including *in vitro* post-hydrolysis tensile testing.

The results of this testing demonstrates that the Quill™ Monoderm™ Knotless Tissue-Closure device, Variable Loop Design, is substantially equivalent to the predicate devices.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-002

Angiotech  
% Ms. Kirsten Stowell  
Regulatory Affairs Manager  
100 Dennis Avenue  
Reading, Pennsylvania 19606

November 20, 2012

Re: K123409

Trade/Device Name: Quill™ Monoderm™ Knotless Tissue-Closure Device, Variable Loop Design

Regulation Number: 21 CFR 878.4493

Regulation Name: Absorbable poly (glycolide/l-lactide) surgical suture

Regulatory Class: Class II

Product Code: GAM

Dated: October 24, 2012

Received: November 5, 2012

Dear Ms. Stowell:

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

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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/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,

**Peter D. Rumm -S**

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

Enclosure

**Section 4 – Indications for Use Statement**

510k number if known:           K123409          

Device Name: Quill™ Monoderm™ Knotless Tissue-Closure Device, Variable Loop Design

Indications for Use:

Quill™ Knotless Tissue-Closure Device comprised of Monoderm™ is indicated for soft tissue approximation where use of an absorbable suture is appropriate.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause  
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\_\_\_\_\_  
(Division Sign-Off)

Division of Surgical Devices

510 (k) Number           K123409