



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

September 10, 2015

Angiotech  
Ms. Hilary Wells  
Regulatory Affairs Manager  
100 Dennis Drive  
Reading, Pennsylvania 19606

Re: K151112

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

Regulation Number: 21 CFR 878.5010

Regulation Name: Nonabsorbable polypropylene surgical suture

Regulatory Class: Class II

Product Code: GAW

Dated: August 9, 2015

Received: August 11, 2015

Dear Ms. Wells:

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

## Indications for Use

510(k) Number (if known)

K151112

Device Name

Quill™ Polypropylene Knotless Tissue-Closure Device, Variable Loop Design

Indications for Use (Describe)

Quill™ Knotless Tissue-Closure Device comprised of Polypropylene is indicated for soft tissue approximation excluding closure of the epidermis.

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.

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**510(k) Summary**

**Date Prepared:** September 8, 2015

**Company:** Angiotech  
100 Dennis Dr.  
Reading, PA 19606

**Contact:** Hilary Wells  
Regulatory Affairs Manager  
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**Device trade name:** Quill™ Polypropylene Knotless Tissue-Closure Device, Variable Loop Design

**Device Common Name:** Nonabsorbable Polypropylene Surgical Suture

**Device classification:** Nonabsorbable Polypropylene Surgical Suture  
Product code, GAW  
21 CFR 878.5010  
Class II

**Legally marketed device to which the device is substantially equivalent:** K130078: Quill™ Polypropylene Knotless Tissue-Closure Device, Variable Loop Design, Size - 0-

**Description of the device:** The Quill™ Polypropylene Knotless Tissue-Closure Device, Variable Loop Design is a sterile, synthetic nonabsorbable tissue-closure device that is intended for use in the closure of soft tissue, excluding closure of the epidermis. It is comprised of high molecular weight, isotactic polypropylene, undyed, or dyed blue with Phthalocyaninato (2-) Copper. 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 Size 0 in various lengths affixed to various needle types.

**Indications for Use:** Quill™ Knotless Tissue-Closure Device comprised of Polypropylene is indicated for soft tissue approximation excluding closure of the epidermis.

**Substantial  
Equivalence:**

The proposed additional diameter sizes, Size 1 & 2, of the Quill™ Polypropylene Knotless Tissue-Closure Device, Variable Loop Design product line have the same material, design, intended use and technological characteristics as the predicate device. The only difference between the proposed and predicate device is the suture diameter.

**Performance tests:**

Non-clinical laboratory performance testing was conducted to confirm that the Quill™ Polypropylene Knotless Tissue-Closure Device, Variable Loop Design conforms to the USP monograph for nonabsorbable sutures (as applicable). 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 device.

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