Section 6 – 510(k) Summary

JAN 2 0 2012

Date Prepared:	December 22, 2011
Company:	Angiotech 100 Dennis Dr. Reading, PA 19606
Contact:	Kirsten Stowell Regulatory Affairs Manager Phone: 610-404-3367 Fax: 610-404-3924 Email: kstowell@angio.com
Device trade name:	Quill™ Quadrahelix Knotless Tissue-Closure Device
Device Common Name:	Polypropylene Non-Absorbable Surgical Suture
Device classification:	Non-Absorbable Polypropylene Surgical Suture Product code, GAW 21 CFR 878.5010 Class II
Legally marketed devices to which the device is substantially equivalent:	K052373: Quill™ Nonabsorbable Polypropylene Barbed Suture
Description of the device:	The Quill™ Quadrahelix Knotless Tissue Closure Device is a non-absorbable isotactic polymer comprised of polypropylene per 21 CFR 878.5010. It is available sterile, undyed (beige) in suture and needle configurations in USP Size 3-0. Each suture has bi-directional quadrahelix barbs along the long axis of the suture monofilament. The Quill™ Quadrahelix Knotless Tissue Closure Device approximates tissue by using the opposing barbs on the suture surface to imbed in the tissues after the surgeon precisely places the suture within the tissues.
Indications for Use:	Quill™ Quadrahelix Knotless Tissue Closure Device is indicated for soft tissue approximation excluding closure of the epidermis.

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Substantial Equivalence: The Quill™ Quadrahelix Knotless Tissue-Closure Device has the same intended use, fundamental scientific technological characteristics, material and size as the predicate device.

Performance tests: Non-clinical laboratory performance testing was conducted to confirm that the Quill™ Quadrahelix Knotless Tissue-Closure Device conforms to the defined product requirements for tensile strength and wound security strength. The results of this testing demonstrates that the Quill™ Quadrahelix Knotless Tissue-Closure Device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

JAN 2 0 2012

Re: K113800
Trade/Device Name: Quill™ Quadrahelix Knotless Tissue Closure Device
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable propylene surgical suture
Regulatory Class: Class II
Product Code: GAW
Dated: December 22, 2011
Received: January 09, 2012

Dear 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 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 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,

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

Enclosure

Indications for Use

510(k) Number (if known): K113800

Device Name: Quill™ Quadrahelix Knotless Tissue Closure Device

Indications for Use:

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

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 K113800