510(k) Summary

OCT 22 2012

Date Prepared: October 16, 2012

Company: Angiotech
100 Dennis Dr.
Reading, PA 19606

Contact: Kirsten Stowell
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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:

K113744:	Quill™ PDO Knotless Tissue-Closure Device (Polydioxanone)
K072028:	Quill™ Self-Retaining System (SRS) comprised of Monoderm™
K100257:	V-Loc™ 90 Absorbable Wound Closure Device

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 Size 2-0 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™ predicate. The proposed device is identical in design to the Quill™ PDO Knotless Tissue-Closure Device predicate. In addition, the propsed 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 simulated use tensile testing in porcine tissue and *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.

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

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

OCT 2 2 2012

Re: K122898
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: September 14, 2012
Received: September 21, 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 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,

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

Enclosure

Section 4 – Indications for Use Statement

510k number if known: K122898

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

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

510(k) Number K122898