Section 5 - 510(k) Summary

K071989
page 1 of 3

1. **Applicant Contact:**

Kevin Bentley
Director of QA & RA
Angiotech
336 Summit Point Drive
Henrietta, NY 14467 USA
Phone: 585-321-8613
Fax: 585-321-1575
Email: kbentley@angio.com

AUG - 6 2007

Date Prepared: July 19, 2007

2. **Name of Device:** Quill™ Self-Retaining System (SRS) comprised of PDO
Common Name: Surgical suture, absorbable, Polydioxanone synthetic
Classification Name: Absorbable Polydioxanone surgical suture
Regulation 21 CFR 878.4840, Product Code NEW

3. **Identification of device(s) to which the submitted claims equivalence:**

The Quill™ Self-Retaining System (SRS) comprised of PDO is substantially equivalent to the following predicate device:

- Quill™ Synthetic Absorbable Polydioxanone Barbed Suture by Quill Medical, Inc., 510(k) K051609
- PDS II Synthetic Absorbable Surgical Suture by Ethicon, Inc. Docket no. 99P-5589.

4. **Device Description:**

The Quill™ Self-Retaining System (SRS) comprised of PDO is a synthetic absorbable suture available in various suture lengths and needle configurations in USP Sizes 3-0 and 4-0. Each suture has bi-directional barbs along the long axis of the suture strand. Barbs allow for tissue approximation without the need to tie surgical knots.

Quill™ SRS is comprised of dyed (D&C Violet No. 2 per 21 CFR 74.3602) polyester [poly (p-dioxanone)], the empirical molecular formula of which is $(C_4H_6O_3)_X$. Polydioxanone polymer has been found to be nonantigenic, nonpyrogenic and elicits only a slight tissue reaction during absorption.

As with interrupted sutures, if the Quill™ Self-Retaining System (SRS) comprised of PDO breaks, the remaining suture passes will hold the wound edges in approximation.

K071989
page 2 of 3

5. Intended Use of the Device:

Quill™ Self-Retaining System (SRS) comprised of PDO is indicated for soft tissue approximation where use of an absorbable suture is appropriate.

6. Characteristics of the device in comparison to those of the predicate devices

Indication for Use and Technology Comparison:

The Quill™ Self-Retaining System (SRS) comprised of PDO is equivalent to the Quill® Synthetic Absorbable Polydioxanone Barbed Suture in its intended use of soft tissue approximation where use of an absorbable suture is appropriate and the technology of using barbs instead of knots to hold the tissue in approximation. The Quill™ Self-Retaining System (SRS) comprised of PDO and the Ethicon PDS II were used in animal studies to assess the capabilities of the barbs to maintain wound approximation as compared to knots.

Material Comparison:

The Quill™ Self-Retaining System (SRS) comprised of PDO is materially equivalent to the predicate devices, Quill® Synthetic Absorbable PDO Barbed Suture and PDS II Synthetic Absorbable Surgical Suture. The Quill™ Synthetic Absorbable PDO Barbed Suture and the predicate devices contain similar materials (monofilament fiber, needles & packaging materials), with same or similar EtO sterilization methods.

K071989
page 3 of 3

The comparison of the predicate devices to the new device is summarized below:

	Quill™ SRS comprised of PDO	Quill® Synthetic Absorbable Polydioxanone Barbed Suture, K051609	PDS II Synthetic Absorbable Surgical Suture, Ethicon, Inc. Docket 99P-5589
Product Code	NEW	NEW	NEW
Suture Characteristic	Synthetic Absorbable PDO	Identical	Identical
Indication for Use	Soft tissue approximation	Identical	Identical
Technique of Deployment	Attached needles	Identical	Identical
Technological Characteristic	Bi-directional barbs along the long axis of the suture monofilament	Identical	Different
Material	PDO	Identical	Identical
Sterilization	EtO	Identical	Identical
Packaging	Device wound onto inner support card, within a foil pouch within a poly/tyvek pouch	Identical	Similar

7. Safety and Performance:

The difference between the Quill™ Self-Retaining System (SRS) comprised of PDO and the above mentioned predicate devices does not raise any questions regarding the safety and effectiveness of the device. The device, as designed, is as safe and effective as its predicate devices.

8. Conclusion

Based on the design, material, performance specification and indications for use discussed herein, Angiotech believes the Quill™ Self-Retaining System (SRS) comprised of PDO is substantially equivalent to predicate devices currently marketed under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2007

Angiotech
% Kevin Bentley, RAC
Director of QA & RA
100 Dennis Drive
Reading, Pennsylvania 19606

Re: K071989
Trade/Device Name: Quill™ Self-Retaining System (SRS comprised of PDO
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: II
Product Code: NEW
Dated: July 19, 2007
Received: July 20, 2007

Dear Mr. Bentley:

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.

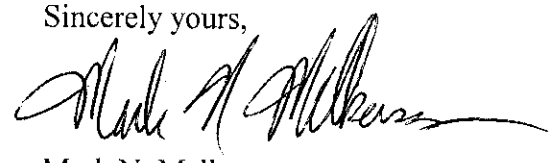
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

Section 4 - Indications for Use Statement

510k number if known: K071989

Device Name: Quill™ Self-Retaining System (SRS) comprised of PDO

Indications for Use:

Quill™ Self-Retaining System (SRS) comprised of PDO 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A Melkerson
K071989

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071989