Section 5 - 510(k) Summary

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1. **Applicant Contact:**

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AUG - 3 2007

Date Prepared: 07-23-07

2. **Name of Device:** Quill™ Self-Retaining System (SRS) comprised of MONODERM™
Common Name: Suture, absorbable, synthetic, polyglycolic acid
Classification Name: Absorbable poly(glycolide/l-lactide) surgical suture Regulation 21 CFR 878.4493, Product Code GAM

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

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

- Quill® Synthetic Absorbable Polydioxanone Barbed Suture by Quill Medical, Inc., 510(k) K051609
- MONODERM™ Synthetic Absorbable Surgical Suture by Surgical Specialties Corp., 510(k) K052437
- MONOCRYL (Poliglecaprone 25) suture, undyed by ETHICON, Inc., 510(k) K964072
- MONOCRYL (Poliglecaprone 25) suture, dyed by ETHICON, Inc., 510(k) K960653

4. **Device Description:**

The Quill™ Self-Retaining System (SRS) comprised of MONODERM™ is a synthetic absorbable monofilament suture prepared from a copolymer of glycolide and e-caprolactone (per 21 CFR 878.4493). It is available sterile, dyed violet (D&C Violet No. 2 per 21 CFR 74.3602) or undyed (beige) in various suture lengths and needle configurations in USP Sizes 0, 2-0 and 3-0. Each suture has bi-directional barbs along the long axis of the suture monofilament.

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The Quill™ Self-Retaining System (SRS) comprised of MONODERM™ 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. Each Quill™ Self-Retaining System (SRS) comprised of MONODERM™ pass provides the security of an interrupted suture strand without the added bulk of a knot. As with interrupted sutures, if the Quill™ Self-Retaining System (SRS) comprised of MONODERM™ breaks, the remaining suture passes will hold the wound edges in approximation.

5. Intended Use of the Device:

Quill™ Self-Retaining System (SRS) comprised of MONODERM™ are 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 device(s)

Indication for Use and Technology Comparison:

The Quill™ Self-Retaining System (SRS) comprised of MONODERM™ 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 MONODERM™ was compared to MONOCRYL in animal studies to assess the capabilities of barbs to knots in order to maintain wound approximation.

Material Comparison:

The Quill™ Self-Retaining System (SRS) comprised of MONODERM™ is equivalent to the MONODERM™ Synthetic Absorbable Surgical Suture manufactured by Surgical Specialties Corp. as *identical* materials (fiber, needles & packaging materials) and sterilization method/sterilization cycle is utilized. In addition, the MONODERM™ Synthetic Absorbable Surgical Suture has an intended use of soft tissue approximation

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

	Quill™ SRS comprised of MONODERM 510(k) ***TBD***	Synthetic Absorbable PDO Barbed Sutures, K051609	MONODERM K052437	MONOCRYL undyed, K964072	MONOCRYL dyed, K960653
Product Code	GAM	Different - NEW	Identical	Identical	Identical
Suture Characteristic	Synthetic Absorbable Monofilament	Identical	Identical	Identical	Identical
Intended Use	Soft tissue approximation	Identical	Identical	Identical	Identical
Technique of Deployment	Attached needles	Identical	Identical	Identical	Identical
Technological Characteristic	Bi-directional barbs along the long axis of the suture monofilament	Identical	Different –Utilizes knots to secure the suture	Different – Utilizes knots to secure the suture	Different – Utilizes knots to secure the suture
Material	PGA-PCL	Different - Polydioxanone	Identical	Similar - Poliglecaprone 25	Similar - Poliglecaprone 25
Sterilization	EO	Identical	Identical	Identical	Identical
Packaging	Device wound onto inner support card, within a foil pouch within a poly/tyvek pouch	Identical	Identical	Identical	Identical

7. Safety and Performance:

The difference between the Quill™ Self-Retaining System (SRS) comprised of MONODERM™ and the above mentioned predicate devices do 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, function and intended use discussed herein, Angiotech believes the Quill™ Self-Retaining System (SRS) comprised of MONODERM™ 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 - 3 2007

Angiotech
% Lois Smart
Regulatory Affairs Manager
100 Dennis Drive
Reading, Pennsylvania 19606

Re: K072028
Trade/Device Name: Quill™ Self-Retaining System (SRS) comprised of MONODERM™
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/$_L$-lactide) surgical suture
Regulatory Class: II
Product Code: GAM
Dated: July 23, 2007
Received: July 24, 2007

Dear Lois Smart:

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: K072028

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

Indications for Use:

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

Prescription Use ___√___ (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)

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

510(k) Number K072028