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Section E - 510(k) Summary

1. **Applicant Contact:**

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Date Prepared: 10-18-04

Submission Contact:

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Regulatory Consultant
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2. **Name of Device:** Quill™ Synthetic Absorbable Barbed Suture
Common Name: Polydioxanone Absorbable Surgical Sutures
Classification Name: Absorbable Polydioxanone Surgical Suture
Regulation 21 CFR 878.4840, Product Code NEW

3. **Identification of the legally marketed device to which the submitted claims equivalence:**

The Quill™ Synthetic Absorbable Barbed Suture is substantially equivalent to predicate device PDS II, a Synthetic Monofilament Absorbable Suture manufactured by Ethicon, Inc. PDS II was reclassified from Class III into Class II as documented in Docket 99P-5589.

4. **Device Description:**

The Quill™ Synthetic Absorbable Barbed Suture is made from the polymer, poly(p-dioxanone). It is available in a dyed form (violet) in various suture lengths and needle configurations. The Quill™ Synthetic Absorbable Barbed Suture degrades or dissolves over time in tissues.

The Quill™ Synthetic Absorbable Barbed Sutures approximate tissues by using the opposing barbs on the suture surface imbedded in the tissues after the surgeon suture pierces the skin and appropriately places the suture within the tissues. The barbs on the Quill suture form an alternative method than knots in conventional suture for holding the two ends of a suture together.

5. **Intended Use of the Device:**

Quill™ Synthetic Absorbable Barbed Sutures are indicated to close easily approximated edges of dermis where use of absorbable sutures is appropriate.

Section E - 510(k) Summary (continued)

6. Technological characteristics of the device in comparison to those of the predicate device:

Parameter	New device Quill™ Synthetic Absorbable Barbed Suture	Predicate device Ethicon Synthetic Monofilament Absorbable PDS II Suture
Chemical	Poly (p-dioxanone)	Poly (p-dioxanone)
USP Sizes	2-0 to 2	9-0 to 2
Oversized Diameter	Yes	Yes
Tensile Strength Equivalence	Quill Size 2-0 Quill Size 0 Quill Size 2	USP Size 4-0 USP Size 3-0 USP Size 0
Approximates Tissues with:	Barbs	Knots
Absorption Profile % Remaining at Time	100 % - 0 months ~ 101 % - 2 months ~ 94 % - 4 months ~ 18 % - 6 months	100 % - 0 months ~ 100 % - 2 months ~ 100% - 4 months ~ 26 % - 6 months
Strength Retention Profile % Strength at Time	100% - 0 week ~ 81% - 2 week ~ 79% - 4 week ~ 42% - 6 week	100% - 0 week ~ 70% - 2 week ~ 50% - 4 week ~ 25% - 6 week

7. Pre-clinical and Clinical Summary

Biocompatibility Summary

Quill Medical performed extensive biocompatibility studies with the Synthetic Monofilament Absorbable PDO Sutures using protocols consistent with appropriate sections of ISO Biological Evaluation of Medical Device Standard 10993. Data presented demonstrate that Quill PDO Sutures are non-toxic, non-hemolytic, non-irritating, non-pyrogenic, non-allergenic, non-sensitizing, non-cytotoxic, non-reactive and biocompatible.

In Vivo Tensile Strength

In vivo tensile strength studies demonstrate that Quill Medical PDO Sutures lose tensile strength during the critical wound healing period: approximately 20% of initial tensile strength is lost in two weeks; 20% is lost in four weeks; 60% is lost in six weeks.

Barb Holding Strength

In vivo barb holding strength of Quill PDO Sutures decreases slightly after implantation, remains relatively constant for approximately four weeks after implantation and retains sufficient tensile strength to approximate tissues during the critical wound period.

Absorption Profile
Quill PDO Sutures are hydrolytically degraded in tissues with approximately 5% of the suture mass being dissolved in two months; 50% being dissolved in four months; and most of the suture mass being dissolved in six months. The degradation products are subsequently absorption by tissues and excreted from the body.

Animal Surgery Summary
Based on observations and results from *in vivo* animal surgery studies Quill PDO Sutures can be adequately used as the sole suture material to close dermal, subcutaneous and muscle incisions.

Clinical Summary
Forty investigators enrolled one hundred and seventy-one patients into a Quill Medical randomized clinical trial at two sites. The demographics for the treatment and control groups were balanced and confirm that randomization procedure was successful. Unblinded investigators evaluated scars for abnormalities at various intervals during and after hospitalization. No full wound dehiscences were noted.

Post-operative pain was assessed and found to be balanced at the observation intervals and presented no clinically significant or statistical differences between the two groups. Administration of post-operative pain medications during the observed recovery period was balanced between the treatment and the control groups.

Scars were clinically assessed using the Hollander Cosmesis scale at 5 weeks post-operatively. There is no clinically significant or statistical difference in the overall unblinded Hollander Cosmesis scores and the individual Hollander Cosmesis components of the treatment and control groups.

Pictures of patients' surgical wounds at the fifth post-operative week were evaluated by an independent blinded plastic surgeon. There is no clinically significant and no statistical difference in the overall blinded and individual component blinded Hollander Cosmesis scores of wound pictures from the treatment and control groups.

There were no clinically significant and no statistical differences between the unblinded and the blinded overall Hollander Cosmesis scores for surgical wounds between the treatment and the control groups.

Twenty-eight (28) patients reported thirty-two (32) adverse events (AEs) during the clinical trial. The AEs were typical of those expected following routine surgery. The distribution of AEs was balanced with no statistically significance difference between the treatment and control groups.

8. Substantial Equivalence Conclusion

Based on the data and table above, the Quill™ Synthetic Absorbable Barbed Suture is substantially equivalent to predicate device PDS II manufactured by Ethicon, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 6 2004

Quill Medical, Inc.
c/o John F. Schaefer, Ph.D.
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, New York 11590

Re: K042075
Trade/Device Name: Quill™ Synthetic Absorbable Barbed Suture
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: II
Product Code: NEW
Dated: September 10, 2004
Received: September 13, 2004

Dear Dr. Schaefer:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section D - Statement of Indications for Use

510k number if known: K042075

Device Name: Quill™ Synthetic Absorbable Barbed Suture

Indications for Use:

Quill™ Synthetic Absorbable Barbed Sutures are indicated to close easily approximated edges of dermis where use of absorbable sutures 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)

Miriam C. Provost

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

510(k) Number K042075