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Section E - 510(k) Summary

1. Applicant Contact:

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Date Prepared: 6-16-05

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 device(s) to which the submitted claims equivalence:

The Quill® Synthetic Absorbable Barbed Suture is substantially equivalent to the following predicate devices:

- For Material Safety and Technological Characteristics:
  - Quill® Synthetic Absorbable Barbed Suture, 510k K042075
  - Contour Midface Opposing Uni-directional Thread by Surgical Specialties Corp., K050548
  - Insorb™ Absorbable Staple by Incisive Surgical, Inc., 510k K024117

- For Indication for Use:
  - Y-Knot Suture Clip by Innovasive Device, Inc., 510k K973313
  - Insorb™ Absorbable Staple by Incisive Surgical, Inc., 510k K024117

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Section E - 510(k) Summary (continued)

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 (minimum opposing barbed segment of 1 3/8" x 1 3/8") and needle configurations. The Quill® Synthetic Absorbable Barbed Suture degrades or dissolves over time in tissue.

The Quill® Synthetic Absorbable Barbed Sutures approximate tissues 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® Synthetic Absorbable Barbed Suture pass provides the security of an interrupted suture strand without the added bulk of a knot. As with interrupted sutures, if the Quill® Synthetic Absorbable Barbed Suture breaks, the remaining suture passes will hold the wound edges in approximation.

5. Intended Use of the Device:

Quill® Synthetic Absorbable Barbed Sutures are indicated for use in soft tissue approximation where use of absorbable sutures is appropriate.

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Section E - 510(k) Summary (continued)

6. Characteristics of the device in comparison to those of the predicate device(s)

Technological Characteristic Comparison:

The Quill® Synthetic Absorbable Barbed Suture is equivalent in technological characteristics to the following predicate devices:

	Quill® Synthetic Absorbable Barbed Suture	Contour Midface Opposing Uni-directional Thread	Insorb™ Absorbable Staple
Technique of Deployment	Subcuticular placement: Needle captures a precise bite on each side of the incision.	Subcuticular placement: Needle placement (or placed by introducer).	Subcuticular placement: Mechanically placed by a stapler to capture a precise bite on each side of the incision.
Technological Characteristic to Approximate Tissue	Bi-directional barbs along the long axis of the suture monofilament catch and cinch to approximate the tissue as does an interrupted suture strand but without the need of a knot.	Opposing unidirectional cogs along the long axis of the suture monofilament to fixate the cheek subdermis in an elevated position.	Cleats of the u-shaped staple approximate tissue after the stapler is retracted.
Predicate	PDS II Suture: N18331	Contour Extended Length Threads K041593	Traditional absorbable staples (two-piece staple and receiver): K915489 & K915693

Intended Use Comparison:

The Quill® Synthetic Absorbable Barbed Suture is equivalent in intended use to the following predicate devices:

	Y-Knot Suture Clip	Insorb™ Absorbable Staple
Intended Use	For use in general soft tissue approximation and/or ligation with #1 and #2 braided polyester suture.	For use in abdominal, thoracic, gynecologic, orthopedic, plastic and reconstructive surgery for the subcuticular closure of skin where an absorbable tissue fastener is desired for temporary tissue approximation.
Performance Data Used for Clearance	Mechanical Performance Testing (Y-Knot suture fixation compared to a knotted suture)	An Animal Study Mechanical Performance Testing Package Testing
Predicate	Ethibond Extra Polyester Suture	Traditional absorbable staples (two-piece staple and receiver)

Section E - 510(k) Summary (continued)

Material Safety Comparison:

The Quill® Synthetic Absorbable Barbed Suture is equivalent in material to the predicate device, Quill® Synthetic Absorbable Barbed Suture, cleared by 510k K042075.

7. Safety and Performance:

By definition, substantial equivalence means that a device has the same intended use and technical characteristics as the predicate device, or has the same intended use and different technological characteristics, but can be demonstrated to be as safe and effective as the predicate device. The difference between the Quill® Synthetic Absorbable Barbed Suture and the predicate devices with similar indications do not raise any questions regarding the safety and effectiveness of the barbed suture. Furthermore, polydioxanone is well-characterized and has been used in predicate devices with similar indications. The device, as designed, is as safe and effective as predicate devices.

Biocompatibility data, simulated use evaluation, results of *in vivo* barb holding and absorption assessments, results of *in vivo* animal studies and human clinical trial results are provided to support the safety and performance of the Quill® Synthetic Absorbable Barbed Suture.

8. Conclusion

Based on the design, materials, function, intended use and performance evaluations discussed herein, Quill Medical believes the Quill® Synthetic Absorbable Barbed Suture 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 4 - 2005

Ms. Lois V. Smart
Director, Quality Assurance and Regulatory Affairs
Quill Medical, Inc.
2505 Meridian Parkway, Suite 150
Research Triangle Park, North Carolina 27713

Re: K051609
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: June 16, 2005
Received: June 17, 2005

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

Sincerely yours,

Mark N. Melkerson
Acting 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: K051609

Device Name: Quill® Synthetic Absorbable Barbed Suture

Indications for Use:

Quill® Synthetic Absorbable Barbed Sutures are indicated for use in soft tissue approximation 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)

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

(510(k) Number K051609