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## Section 5 - 510(k) Summary

MAY 16 2013

**Date Prepared:** May 10, 2013

**Company:**
Surgical Specialties Corporation, dba Angiotech
100 Dennis Dr.
Reading, PA 19606

**Contact:**
Kirsten Stowell
Regulatory Affairs Manager
Phone: 610-404-3367
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Email: kstowell@angio.com

**Device trade name:**
Sharpoint™ Polypropylene Suture
Look™ Polypropylene Suture
Quill™ Polypropylene Knotless-Tissue Closure Device

**Device Common Name:** Nonabsorbable polypropylene surgical suture

**Device classification:**
Nonabsorbable polypropylene surgical suture
Product code, GAW
21 CFR 878.5010
Class II

**Legally marketed devices to which the device is substantially equivalent:**

| | |
|---|---|
| P870064<br>K904906<br>K930825 | Sharpoint Polypropylene Nonabsorbable Surgical Suture |
| K903584<br>K926588 | Look Inc. Polypropylene Nonabsorbable Surgical Sutures |
| K052373<br>K113800<br>K130078 | Quill™ Nonabsorbable Polypropylene Barbed Suture |

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**Description of the device:**

The Polypropylene Surgical Suture and Quill™ Polypropylene Knotless Tissue-Closure Devices are sterile, synthetic nonabsorbable surgical suturing devices that are intended for use in the closure of soft tissue (see below). They are comprised of high molecular weight, isotactic polypropylene, undyed, or dyed blue with Phthalocyaninato (2-) Copper. The proposed modification is a change in supplier of the polypropylene resin raw material. The devices are supplied either single or double-armed with various needle types, and are available in USP diameter Sizes 2 through 11-0, as applicable.

The Quill™ Polypropylene devices are designed with either small opposing bi-directional or uni-directional barbs along the long axis of the suture monofilament. The uni-directional products contain a welded primary loop and secondary loop design at the distal end, opposite the attached needle.

**Indications for Use:**

Polypropylene suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Quill™ Knotless Tissue-Closure Device comprised of Polypropylene is indicated for soft tissue approximation excluding closure of the epidermis.

**Substantial Equivalence:**

The Polypropylene Surgical Suture devices have been demonstrated to be identical in material, design and intended use to the predicate Polypropylene Surgical Suture devices.

The Quill™ Polypropylene Knotless Tissue-Closure devices have been demonstrated to be identical in material, design and intended use to the predicate Quill™ Polypropylene devices.

**Performance tests:**

Non-clinical laboratory performance testing was conducted to confirm that the Polypropylene Surgical Sutures and Quill™ Polypropylene Knotless Tissue-Closure devices conform to the USP monograph for nonabsorbable sutures for diameter and tensile strength (as applicable). This testing was performed in accordance with FDA's Class II Special Controls Guidance Document: Surgical Sutures, Issued June 3, 2003.

Additional chemical characterization testing and biological risk assessment was conducted in order to evaluate the chemical equivalency of the polypropylene raw material. The results of this testing demonstrates that the Polypropylene Surgical Suture and Quill™ Polypropylene Knotless Tissue-Closure devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

May 16, 2013

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

Re: K131224
Trade/Device Name: Sharpoint™ Polypropylene Surgical Sutures
Look™ Polypropylene Surgical Sutures
Quill™ Polypropylene Knotless Tissue-Closure Devices
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: Class II
Product Code: GAW
Dated: April 26, 2013
Received: April 30, 2013

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,

For

Peter D. Rumm -S

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

Enclosure

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**Section 4 – Indications for Use Statement**

510k number if known: _____

Device Name: Polypropylene Sutures

Indications for Use:

Polypropylene suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

| | | |
|---|---|---|
| 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131224

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**Section 4 – Indications for Use Statement**

510k number if known: _____

Device Name: Quill™ Polypropylene Knotless Tissue-Closure Device

Indications for Use:

Quill™ Knotless Tissue-Closure Device comprised of Polypropylene is indicated for soft tissue approximation excluding closure of the epidermis.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
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