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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS SUBSTANTIAL EQUIVALENCY

Submitter:	Surgical Specialties Corporation
Address:	100 Dennis Drive Reading, PA 19606
Telephone:	610 404 1000, ext. 2231
Contact Person:	Elizabeth Lazaro Regulatory Affairs Specialist
Date Prepared:	October 20, 2005

Name of Device:	Contour Thread
Common / Usual Classification Name:	GAW Suture, Non Absorbable, Synthetic, Polypropylene
Predicate Device:	Contour Threads K041593, K050548, K050247 and K042856 as previously submitted by Surgical Specialties Corporation and Predicate K042075 and K051609 as submitted by Quill Medical for Barb design.
Indications For Use:	Fixation and Elevation as previously submitted, see indications section of this submission of approved Contour Thread 510 (k)'s: K041593 Midface Extended Length K050548 Midface Opposing Uni-directional K050247 Neck Lift K042856 Brow Lift

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

Device Description	The Contour Threads are a clear, nonabsorbable, sterile, surgical strand of polypropylene. The base product is USP size 2-0 polypropylene suture material. The Threads may incorporates a Uni-directional or Bi-directional barbed design. The Threads will be supplied with needles attached to both ends. The needles are made of 400 series stainless steel. The threads are supplied sterile for single use.
Technological Characteristics:	The Polypropylene material used for the Contour Threads is commonly used in medical applications and have been proven to be biocompatible. Bench and animal evaluations have demonstrated the device to be safe and effective. It is equivalent to other 510 (k) approved surgical sutures and identical to Surgical Specialties' Polypropylene Surgical Sutures, PMA 870064.
Performance Data:	Comparison of Holding Tissue Force in an *Ex Vivo* Test in pigs.
Substantial Equivalence	The Contour Thread is identical to the intended use as previously submitted by Surgical Specialties Corporation. The Contour Thread barb design is the same as the Quill design approved in the 510(k) K042075 and K051609.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 6 2005

Elizabeth Lazaro
Regulatory Affairs Specialist
Surgical Specialties Corporation
100 Dennis Drive
Reading, Pennsylvania 19606

Re: K052962
Trade/Device Name: The Contour Necklift Threads™, The Contour Midface Opposing Uni-Directional Threads™, Contour Forehead/Browlift Thread™, Featherlift™ Extended Length Length Aptos Thread
Regulation Number: 21 CFR878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: II
Product Code: GAW
Dated: October 20, 2005
Received: October 21, 2005

Dear Ms. Lazaro:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are 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 devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to such additional controls. Existing major regulations affecting your devices 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 devices comply 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 devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your device and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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/industry/support/index.html.

Sincerely yours,

Barbara Melkerson for

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

Enclosure

K052962

Indications for Use

510(k) Number (if known): K052962

Device Name: The Contour Necklift Threads™

Indications For Use:

The Contour Necklift Threads™ are indicated for use in Necklift surgery. The Contour Necklift Threads™ are specifically indicated for use to fixate and Elevate the subdermis to the deep fascia of the retromastoid area.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for MKM

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

510(k) Number K052962

K052962

Indications for Use

510(k) Number (if known): K052962

Device Name: The Contour Midface Opposing Uni-Directional Threads™

Indications For Use:

The Contour Midface Opposing Uni-Directional Threads™ are indicated for use in midface suspension surgery to fixate the cheek subdermis in an elevated position.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brechner MKM

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

510(k) Number K052962

K052962

Indications for Use

510(k) Number (if known): K052962

Device Name: Contour Forehead/Browlift Thread™

Indications For Use:

The Contour Forehead/Browlift Thread™ is indicated for use in browplasty surgery.

The Contour Forehead/Browlift Thread™ is specifically indicated for use to fixate the subdermis to the periosteum of the cranium in browplasty.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchholz for MKM

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

510(k) Number K052962

K052962

Indications for Use

510(k) Number (if known): K052962

Device Name: Featherlift™ Extended Length Length Aptos Thread

Indications For Use:

The Featherlift™ Extended Length Aptos Thread is indicated for use in midface suspension surgery to fixate the cheek subdermis in an elevated position.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler for MXM

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

510(k) Number K052962