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SURGICAL SPECIALTIES CORPORATION
Precision & Healing Technologies

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:	January 31, 2005

Name of Device:	Contour Necklift Threads™
Common / Usual Classification Name:	GAW Suture, Non Absorbable, Synthetic, Polypropylene

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Predicate Device:	Contour Midface Threads™ K041593 Contour Browlift Threads™ K042856 Prolene™ Sutures N16374

Indications For Use:	The Contour Necklift Thread™ is indicated for use in Necklift Surgery. The Necklift Contour Threads are specifically indicated for use to fixate and elevate the subdermis to the deep fascia of the retromastoid area.

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

Device Description	The Contour Necklift Threads™ are a clear, nonabsorbable, sterile, surgical strand of polypropylene. The base product is USP size 2-0 polypropylene suture. The 25centimeter length thread incorporates a unidirectional barbed section 10 centimeters long from the distal end. The Threads will have a 7inch straight needle attached to the distal end and a 26 mm curved needle attached to the proximal end. The threads are supplied sterile for single use.
Technological Characteristics:	The Polypropylene material used for the Contour Necklift Threads™ is commonly used in medical applications and has been proven to be biocompatible. Bench and animal evaluations have demonstrated the device to be safe and effective. These characteristics are the same for Surgical Specialties Corporation's Contour Threads as presented in the predicate 510 (k)'s. There is no change in chemistry, material or composition.
Performance Data	Physical testing was conducted on the thread to USP 27 tensile strength, force required to remove after implantation and Biocompatibility for permanent implantation, ISO 10993.

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Substantial Equivalence	The Contour Necklift Thread™ is equivalent in the intended use to the predicate devices,The Contour Midface and Browlift Threads. The Contour Necklift Threads uses the same suture material as the predicate devices, Contour Midface and Browlift Threads. The use in different anatomical sites for the Necklift, Brow lift and Midface applications does not change the safety and effectiveness. The Contour Necklift Threads also have a predicate device in the use of the PROLENE suture for what has been established as a safe and effective Gold Standard Surgical Procedure for Necklift in the last 2 decades, as described in this submission. The substantial equivalence determination is equivalent for these indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 - 2005

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

Re: K050247
Trade/Device Name: The Contour Necklift Threads™
Regulation Number: 21 CFR 878.5010
Regulation Name: Non-absorbable synthetic polypropylene suture
Regulatory Class: II
Product Code: GAW
Dated: January 31, 2005
Received: February 2, 2005

Dear Ms. Lazaro:

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/industry/support/index.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

K050247

Indications for Use

SURGICAL SPECIALTIES CORPORATION
Incision & Healing Technologies

510(k) Number (if known):

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.

Miriam C Hurst

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

510(k) Number K050247

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)

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