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APR - 1 2005

SURGICAL SPECIALTIES CORPORATION
Healing Technologies

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS
SUBSTANTIAL EQUIVALENCY

Submitter: Address:	Surgical Specialties Corporation 100 Dennis Drive Reading, PA 19606
Telephone: Contact Person:	610 404 1000, ext. 2231 Elizabeth Lazaro Regulatory Affairs Specialist
Date Prepared:	February 28, 2005

Name of Device:	Contour Midface Opposing Uni-directional Threads
Common / Usual Classification Name:	GAW Suture, Non Absorbable, Synthetic, Polypropylene
Predicate Device:	Contour Extended Length Threads K041593
Indications For Use:	The Contour Midface Opposing Uni-directional Thread is indicated for use in midface suspension surgery to fixate the cheek subdermis in an elevated position.

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

Device Description	The Contour Midface Opposing Uni-Directional Threads are a clear, nonabsorbable, sterile, surgical strand of polypropylene. The base product is USP size 2-0 polypropylene suture material. The 45centimeter length incorporates a Uni-directional-barbed design with center of the thread being smooth for a distance of a nominal two inches. The Threads will be supplied with 7 inch 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 Midface 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:	Physical testing was conducted on the thread to USP 27 for tensile strength.
Substantial Equivalence	The Contour Midface Opposing Uni-Directional Thread is identical in the intended use to the predicate The Contour Extended Length Threads. The Contour Midface Opposing Uni-Directional Thread uses the same suture material shown to have tensile strength and biocompatibility suitable for this application. The approved suture material is Polypropylene. The Contour Midface Opposing Uni-Directional Threads intended use is in midface suspension surgery to fixate the cheek subdermis in an elevated position.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2005

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

Re: K050548
Trade/Device Name: The Contour Midface Opposing Uni-Directional Threads™
Regulation Number: 21 CFR 878.5010
Regulation Name: Non-absorbable synthetic polypropylene suture
Regulatory Class: II
Product Code: GAW
Dated: March 1, 2005
Received: March 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, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K050548

Indications for Use

510(k) Number (if known):

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 X 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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