DEC - 3 2004

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS SUBSTANTIAL EQUIVALENCY

Submitter:	Surgical Specialties Corporation
Address:	100 Dennis Drive Reading, PA 19606
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Contact Person:	Elizabeth Lazaro Regulatory Affairs Specialist
Date Prepared:	October 14, 2004

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

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Predicate Device:	Coapt Endotine Forehead Device K014153 Featherlift Extended Length Thread (Contour Threads™) K041593

Indications For Use:	The Contour Forehead/Browlift Thread™ is indicated for use in browplasty surgery. The Contour Forehead/ Browlift Thread™ is indicated for use to fixate the subdermis to the periosteum of the Cranium in browplasty.

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

Device Description	The Contour Forehead/Browlift Threads™ are a clear, nonabsorbable, sterile, surgical strand of polypropylene. The base product is USP size 2-0 polypropylene suture material. The 20 centimeter length incorporates a unidirectional-cogged section 10 centimeters long from the distal end. The 12 centimeter length incorporates a bi-directional design from the center. Both Unidirectional and Bidirectional Threads will have a 4 inch needle attached to the distal ends, with a 26 mm curved needle attached to the proximal end of the Unidirectional Thread and a 1 1/2 inch straight needle attached to the proximal end of the Bidirectional Threads. The threads are supplied sterile for single use.
Technological Characteristics:	The Polypropylene material used for the Contour Forehead/Browlift 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. It is equivalent to other 510 (k) approved surgical sutures and identical to Surgical Specialties' Polypropylene Surgical Sutures, PMA 870064.
Substantial Equivalence	The Contour Forehead/ Browlift Thread™ is identical in the intended use to the predicate Endotine Forehead device. The Contour Forehead/Browlift Thread™ uses the same suture material as the predicate Featherlift Extended Length Thread (Contour Threads™).The approved suture material is Polypropylene. The Contour Forehead/Browlift Threads™ intended use is in browplasty surgery to fixate the subdermis to the periosteum of the cranium in browplasty.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 3 2004

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

Re: K042856
Trade/Device Name: Contour Forehead / Browlift Threads™
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical structure
Regulatory Class: II
Product Code: GAW
Dated: October 14, 2004
Received: October 15, 2004

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/dsma/dsmamain.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

K042856

Indications for Use

510(k) Number (if known): K042856

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 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)

Miriam C. Provost

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

510(k) Number K042856