SEP 20 2004

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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 Betty Lazaro Regulatory Affairs Specialtist
Date Prepared:	June 10, 2004

Name of Device:	Featherlift™ Extended Length Aptos Threads
Common / Usual Classification Name:	GAW Suture, Non Absorbable, Synthetic, Polypropylene
Predicate Device:	Coapt Endotine Midface ST 4.5 device K032698
Indications For Use:	Featherlift Aptos Extended Length Threads are 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 threads are a blue, nonabsorbable, sterile, surgical strand of polypropylene. The product is USP size 2-0 polypropylene suture material 25 centimeters in length and incorporates a unidirectional-cogged section 10 centimeters long from the distal end. A 2 ¾ straight taper cutting needle made of 400 series stainless steel will be swedged to the proximal end. An introducer made of 18 gauge stainless steel will be included for placement of the Threads. The threads and the introducer are supplied sterile for single use.
Technological Characteristics:	The Polypropylene sutures used PMA 870064, K904906 for the fabrication of FeatherLift™ Extended Length Aptos Threads are commonly used in medical applications where they are implanted for tissue approximation in the body indefinitely. Bench and animal evaluations have demonstrated the Featherlift Extended Length Aptos Threads to be safe and effective.
Performance Data:	Physical testing was conducted on the thread to USP 27 for tensile strength, force required to remove after implantation and Biocompatability for permanent implantation, ISO 10993.

Substantial Equivalence	The Featherlift™ Extended Length Aptos Thread is equivalent in use as its predicate device Endotine Midface ST 4.5 having the same intended use and indication for use except for the surgical technique of subperiosteal deployment. The fixation of subcutaneous tissue and elevation for both devices are achieved by tacking to the temporal fascia. They are anchored by suturing and tying to that fascia. The fixation surface area of the Featherlift Aptos Thread is more uniform, spread out over the entire midface providing a greater surface area of fixation compared to the Endotine Midface. The Material of the Featherlift Aptos Thread is made from a non absorbable polypropylene suture and will maintain its fixation indefinitely compared to the midface suspension device that is fabricated from a PGA equivalent material that looses significant strength and mass by 5 months. Therefore, the Featherlift Aptos Thread is substantially equivalent and offers some advantages over the predicate device, the Endotine Midface ST4.5.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 20 2004

Mr. Richard G. Jones
Vice President, Regulatory Affairs/Quality Assurance
Surgical Specialties Corporation
100 Dennis Drive
Reading, Pennsylvania 19606

Re: K041593
Trade/Device Name: Featherlift™ Extended Length Aptos Thread
Regulation Number: 21 CFR 878.5010
Regulation Name: Polypropylene suture
Regulatory Class: II
Product Code: GAW
Dated: September 7, 2004
Received: September 9, 2004

Dear Mr. Jones:

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 (301) 594-4659. 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,

for Miriam C. Provost

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

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Indications for Use

510(k) Number (if known):

Device Name: Featherlift™Extended 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)

Miriam C. Provost

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

510(k) Number K041593