OCT 19 2004

Section 4: 510(k) Summary

510(k) Number: _____

Manufacturer: Opus Medical, 27127 Calle Arroyo, Suite 1924
San Juan Capistrano, CA. 92675

Contact Person: Laura Kasperowicz, Ph: (949) 234-0400, Fax: 234-0493
E-Mail: Lkasperowicz@opusmedical.com

Date Prepared: July 26, 2004

Device Information:

Trade Name: **Opus SpeedStitch™ Suture Device**

Common Name: Suture Punch; Endoscopic Accessories

Classification Name: Endoscope and Accessories per
21 CFR 876.1500

Indications for Use:

Is indicated for use for in placement of suture through soft tissue in endoscopic and other limited access procedures.

Substantial Equivalence

The Opus SpeedStitch™ Suture Device is substantially equivalent in design and intended use to the existing Opus SmartStitch® Suture Device.

Device Description:

The Opus Medical SpeedStitch™ Suture Device is intended for use in endoscopic procedures as well as other limited access open procedures for the purpose of suturing soft tissues. The general design technology of the SpeedStitch™ is based on a hand held, manually powered suture punch for the delivery of a suture needle through soft tissue. The device delivers a simple stitch using USP #2 braided suture.

SECTION 5: CLASS III CERTIFICATION AND SUMMARY

Not applicable. This device is Class II.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2004

Ms. Laura N. Kasperowicz
Regulatory Affairs
Opus Medical, Inc.
27127 Calle Arroyo, Suite 1924
San Juan Capistrano, California 92675

Re: K042031
Trade/Device Name: Opus SpeedStitch™ Suture Device
Regulation Number: 21 CFR 878.5000
Regulation Name: Synthetic Non-absorbable PET suture
Regulatory Class: II
Product Code: GAT
Dated: September 28, 2004
Received: September 30, 2004

Dear :

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

K042031

SECTION 3: STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Opus SpeedStitch™ Suture Device

Indications for Use:

Is indicated for use for in placement of suture through soft tissue in endoscopic and other limited access procedures.

Prescription Use X OR Over-The-Counter Use _____
(Per CFR 801.109)

(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 K042031