FEB 2 5 2004

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:

Stryker Leibinger Colorado MicroDissection Needle®

K033232

General Information

Proprietary Name:	Stryker Leibinger Colorado MicroDissection Needle®
Common Name:	Electrode, Electrosurgical
Proposed Regulatory Class:	Class II
Device Classification:	GEI 878.4400, Electrosurgical Electrode
Submitter:	Stryker Leibinger 4100 East Milham Avenue Kalamazoo, MI 49001 269-323-4226
Submitter's Registration #:	1811755
Manufacturer's Registration #:	9616696
Contact Person:	Wade T. Rutkoskie Associate Manager RA QA Phone: 269-323-4226 Fax: 269-323-4215

Intended Use

The Colorado MicroDissection Needle® is a monopolar electrosurgical instrument used for precision soft tissue dissection. Including but not limited to tonsillectomy and blepharoplasty. It is a single-use device intended for cutting, dissecting and cauterizing soft tissue. The Colorado MicroDissection Needle is not intended for use in the central nervous system or in the central circulatory system.

Substantial Equivalence

EQUIVALENT PRODUCTS:

The Stryker Colorado MicroDissection Needle is equivalent to the previous version of the product cleared under K000348, and the product manufactured by Colorado Biomedical, Inc. and cleared with K881763. Equivalent product information is found in Appendix 3.

Wade T. Rutkoskie

Wade T. Rutkoskie
Associate Manager RA QA
Stryker Instruments
Leibinger Division

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 5 2004

Mr. Wade T. Rutkoskie
Associate Manager RA, QA
Stryker Leibinger
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K033232
Trade/Device Name: Stryker Leibinger Colorado MicroDissection Needle®
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 9, 2003
Received: December 10, 2003

Dear Mr. Rutkoskie:

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 Mark N. Melkerson

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

510(K) Number (if known): K033232

Device Name: Colorado MicroDissection Needle®

Intended Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K033232

Prescription Use ✓ or Over-The-Counter Use _____
(per 21 CFR 801.109)

(Optional Format 1-2-96)