MAY 29 1998

K974771

11. Premarket Notification 510(k) Safety and Effectiveness Summary

Stryker SE5 Arthroscopy System with HERMES OR Control Center System 510(k) Summary

Stryker Endoscopy is submitting the following safety and effectiveness summary.

1) Submitter Information

Stryker Endoscopy
2590 Walsh Avenue
Santa Clara, CA 95051
(408) 567-2179
Contact: Salmaan Hameed
Prepared December 18, 1997

2) Name of Device:

Proprietary Name: SE5 Arthroscopy System with HERMES Voice Control
Common Name is SE5 Arthroscopy System with HERMES Voice Control
Classification Name: Surgical instrument motors and accessories/attachments

3) Substantially equivalent to SE 5 Shaver 510(k) 941333, AESOP 510(k)'s K931783 and K960655

4) The SE5 Arthroscopy and Small Joint Debrider Systems are electrically powered instrumentation specifically designed for intra-articular debridement. A common control console powers the SE5 Shaver Handpiece. The SE5 Arthroscopy System is intended to be used by surgeons in orthopedic joints, including the knee, shoulder, ankle, elbow, wrist, hip and tempomandibular joint. It will be used to resect tissue and bur bone. The voice activation system is substantially equal to AESOP voice activation system. With this upgrade there are no new issues of safety and effectiveness.

5) The Stryker SE5 Arthroscopy System with HERMES OR Control Center is designed and tested to the following Computer Motion and voluntary standards.

- IEC 601-1 Second Edition 1988 International Standard for Medical Electrical Equipment
- IEC 601-1 Amendment 1 1991 International Standard for Medical Electrical Equipment
- IEC 601-2-18 First Edition 1990 International Standard for Medical Electrical Equipment
- UL 2601-1
- EMC Directive European Union 89/336/EEC
- CAN/CSA-C22.2 NO. 601.1-M90 & NO. 601.2.18-92
- HERMES Voice control System Functional Test Requirements

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 1998

Mr. Salmaan Hameed
Project Engineer
Stryker Endoscopy
2590 Walsh Avenue
Santa Clara, California 95051

Re: K974771
Trade Name: Stryker SE5 Arthroscopy System With 'Hermes' Voice Control
Regulatory Class: II
Product Code: GCJ
Dated: April 3, 1998
Received: April 7, 1998

Dear Mr. Hameed:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K974771

Device Name: Stryker SE5 Arthroscopy System with 'Hermes' voice control

Indications For Use:

Indications for use of the SE5 Small Joint Shaver in the wrist are any need for morselization of tissue within the joint. Cutters will be used to debride synovitis, articular cartilage flaps, or torn ligaments when surgeons deem resection appropriate. Burs are indicated for management of osseous lesions such as eburnated articular surfaces or osteophytes.

(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 Devices
510(k) Number K974771

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)