

## 9 Premarket Notification 510(k) Safety and Effectiveness Summary

### Stryker HERMES-Ready™ Total Performance System 510(k)

Stryker Instruments is submitting the following safety and effectiveness summary.

1) Submitter Information:

Stryker Instruments  
4100 E. Milham Ave.  
Kalamazoo, MI 49001  
(616) 323-7700  
Contact: Nicole Petty  
Prepared: March 12, 1999

2) Name of Device:

Proprietary Name: Stryker HERMES-Ready™ Total Performance System  
Common Name is Stryker HERMES-Ready™ Total Performance System  
Classification Name: Surgical instrument motors and accessories/attachments

3) Substantially equivalent to Stryker SE5 Arthroscopy System with Hermes Voice Control 510(k) 974771, HERMES™ 510(k)'s K973700 and K980787, and Stryker Total Performance System K942956, K943540, K943589, K943563/S2, K943541.

4) The Stryker HERMES-Ready™ Total Performance System is intended for use in the cutting, drilling, reaming, decorticating, and smoothing of bone and other bone related tissue in a variety of surgical procedures. Procedures for use on bone are often used in orthopedics, dental, oral surgery, maxillofacial, plastics, ENT, and neurological. It is also used in the placement of screws, wires, pins, and other fixation devices. It can also be used to cut metal. The endoscopic applications with TPS include 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.

5) The Stryker HERMES-Ready™ Total Performance System will be designed and tested to the following voluntary standards.

- IEC 601-1 Medical Electrical Equipment – General Requirements for Safety
- IEC 601-1-1 Medical Electrical Equipment – Collateral Standard: Safety Requirements for Electrical Systems
- IEC 601-1-2 Medical Electrical Equipment – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
- IEC 601-1-4 Medical Electrical Equipment – Collateral Standard: Requirements for Programmable Electronic Systems
- UL 2601-1 – UL Standard for Safety for Medical Electrical Equipment – General Requirements for Safety (US Deviations for IEC 601-1)
- CAN/CSA-C22.2 NO. 601.1-M90 – Medical Electrical Equipment General Requirements for Safety: A National Standard of Canada (Canadian Deviation for IEC 601-1)

K991696

## **10 Stryker HERMES-Ready™ Total Performance System Additional Appendix to User Manual**

All other sections of the current User's Manual will remain unchanged.

Please refer to Tab A for the proposed appendix and current user instructions.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 25 1999

Ms. Nicole Petty  
Regulatory Affairs Analyst  
Stryker Instruments  
4100 East Milham Avenue  
Kalamazoo, Michigan 49001

Re: K991696  
Trade Name: Stryker HERMES-Ready™ Total Performance System  
Regulatory Class: II  
Product Code: DZI, EIA, ERL, HBC, HBE, HWE  
Dated: September 16, 1999  
Received: September 17, 1999

Dear Ms. Petty:

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.

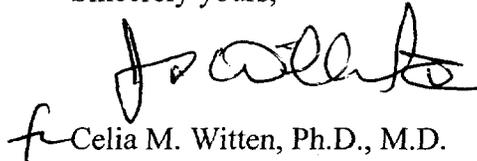
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Ms. Nicole Petty

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C".

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): K991696

Device Name: Stryker HERMES-Ready™ Total Performance System

**Indications For Use:**

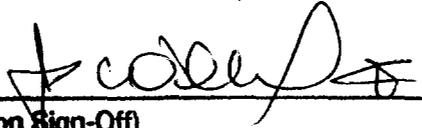
The Stryker HERMES-Ready™ Total Performance System is intended for use in the cutting, drilling, reaming, decorticating, and smoothing of bone and other bone related tissue in a variety of surgical procedures. Procedures for use on bone are often in orthopedics, dental, oral surgery, maxillofacial, plastics, ENT, and neurological. It is also used in the placement of screws, wires, pins, and other fixation devices. It can also be used to cut metal.

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PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K991696

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_