K973700

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

HERMES OR Control Center System 510(k) Summary

In accordance with 21 CFR section 807.92 Computer Motion is submitting the following safety and effectiveness summary.

1) Submitter Information

FEB 24 1998

Stryker Endoscopy
2590 Walsh Avenue
Santa Clara, CA 95051
(408) 567-2179
Contact: Carlos Gonzalez
Prepared September 17, 1997

and

Computer Motion. Inc.
130-B Cremona Drive
Goleta, CA 93117
805-685-3729
Contact: Douglas Bueschel
Prepared: September 17, 1997

2) Name of Device:

Proprietary Name: HERMES Operating Room Control Center and Accessories
Common Name is HERMES
Classification Name: Laparoscope, General & Plastic Surgery

3) Substantially equivalent to AESOP 510(k)'s K931783 and K960655; Model 882 Camera: K820624; Quantum 5000 Light Source: K961971.

4) The HERMES Operating Room Control Center is a computer-driven system whose basic function is offer the additional option for surgeon selection of attachment device parameter settings utilizing voice control.

The intended use of the HERMES OR Control Center is a Voice Control system whose function is to allow for simplified and direct control of Stryker Endoscopy 882 Camera and Quantum 5000 Light Source settings by the surgeon, thereby eliminating the necessity of using multiple input interfaces now common in the operating room, or relying upon verbal communications between the surgeon and other personnel in the OR in order to adjust Stryker Endoscopy 882 Camera and Quantum 5000 Light Source.

The HERMES OR Control Center and the Stryker Endoscopy 882 Camera and Quantum 5000 Light Source are indicated for use in general thoracoscopy, general cardiothoracic surgery, general laparoscopy, nasopharyngoscopy, ear endoscopy, and sinuscopy. A few examples of the more common surgical procedures where this systems could be used are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic & thorascopic anterior spinal fusion, decompression fixation, wedge resection, lung biopsy, pleural biopsy, dorsal sympathectomy, pleurodesis, internal mammary artery dissection for coronary artery bypass, coronary artery bypass grafting where endoscopic visualization is indicated and examination of the evacuated cardiac chamber during performance of valve replacement. The users of the HERMES OR Control Center are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

5) The 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 System Functional Test Requirements

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Douglas P. Bueschel
Director, Regulatory Affairs and Quality Assurance
Computer Motion, Inc.
130-B Cremona Drive
Goleta, California 93117

FEB 24 1998

Re: K973700
Trade Name: Hermes Operating Room Control Center
Regulatory Class: II
Product Code: GCJ
Dated: January 2, 1998
Received: January 5, 1998

Dear Mr. Bueschel:

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,

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): K973700

Device Name: Hermes Operating Room Control Center

Indications For Use:

4. Indications For Use

The HERMES OR Control Center is indicated for use with Stryker Endoscopy 882 Camera and Quantum 5000 Light Source that is used in general laparoscopy, nasopharyngoscopy, ear endoscopy, and sinuscopy where a laparoscope/endoscope is indicated for use. A few examples of the more common endoscopic surgeries are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic & thorascopic anterior spinal fusion, decompression fixation, wedge resection, lung biopsy, pleural biopsy, dorsal sympathectomy, pleurodesis, internal mammary artery dissection for coronary artery bypass, coronary artery bypass grafting where endoscopic visualization is indicated and examination of the evacuated cardiac chamber during performance of valve replacement. The users of the HERMES ORCC are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

(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 K973700

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)