MAY 27

K991635

10. 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

Computer Motion, Inc.
130-B Cremona Drive
Goleta, CA 93117

Contact: David Thomas
Prepared: May 11 , 1999

2) Name of Device:

Proprietary Name: HERMES™ Operating Room Control Center and Accessories
Common Name is HERMES Operating Room Control Center
Classification Name: Laparoscope for Use in General and Plastic Surgery, Regulation Number 876.1500, Class II.

3) Substantially equivalent to HERMES Operating Room Control Center and Accessories K980787

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 intent of the HERMES OR Control Center is to allow for simplified and more direct control of medical device settings by the physician, thereby eliminating the necessity of using the various interfaces existing on the Stryker Endoscopy 882 Camera, Quantum 5000 Light Source, Stryker SE5 Shaver, W.O.M. 20L Insufflator, W.O.M. 2.0L Arthroscopy Pump and Berchtold Surgical Lights in the Operating setting, or relying upon verbal communications between the surgeon and other personnel in the operation room in order to adjust surgical equipment.

The HERMES OR Control Center is indicated for use with Stryker Endoscopy 882 Camera, Quantum 5000 Light Source, Stryker SE5 Shaver, W.O.M. 20L Insufflator, W.O.M. 2.0L Arthroscopy Pump and Berchtold Surgical Lights. It can be 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 symph 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 in 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

5) The HERMES OR Control Center is designed and tested to the following Computer Motion and voluntary standards.

IEC 601-1 Second Edition 1990 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
Conducted & Radiated Emission EN55022/A1: 1995
Immunity Tests EN61000-4-2: 1995; EN61000-4-3: 1995; EN50140:1994; EN61000-4-4:1995; EN61000-4-5:1995; EN61000-4-6:1995.
CAN/CSA-C22.2 NO. 601.1-M90 & NO. 601.2.18-92

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 1999

Mr. David U. Thomas
Regulatory Affairs Specialist
Computer Motion
130-B Cremona Drive
Goleta, California 93117

Re: K991635
Trade Name: HERMES™ Operating Room Control Center and Accessories
Regulatory Class: II
Product Code: GCJ
Dated: May 11, 1999
Received: May 12, 1999

Dear Mr. Thomas:

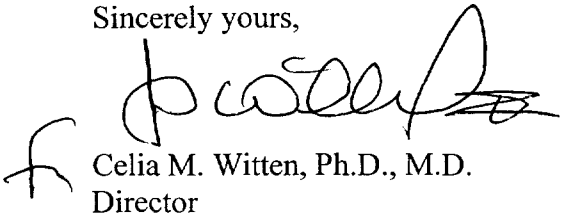
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K991635

Device Name: HERMES™ with Berchtold Lights

Indications For Use:

The HERMES OR Control Center is indicated for use with Stryker Endoscopy 882 Camera, Quantum 5000 Light Source, Stryker SE5 Shaver, W.O.M. 20L Insufflator, W.O.M. 2.0L Arthroscopy Pump and Berchtold Surgical Lights. It can be 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 K991635

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)