K022897

CONFIDENTIAL

HERMES™ O.R. Control Center
510(k) Summary of Safety and Effectiveness

OCT 11 2002

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: Cathy Stupak, Ph.D.

2) Name of Device:

Proprietary Name:	HERMES™ O.R. Control Center
Common Name:	HERMES
Classification Name:	Laparoscope for Use in General and Plastic Surgery
Regulation Number:	876.1500
Class:	Class II.

3) Substantially equivalent to HERMES O.R. Control Center, K973700, and the more recent 510(k), K003222, for HERMES control of the Valleylab Force FX™ Electro-surgical Unit.

4) The HERMES O.R. Control Center is a computer-driven system whose basic function is offer voice control of ancillary devices.

The HERMES™ O.R. Control Center and Port Expander is indicated for use with Stryker Endoscopy 882 Camera, Stryker Quantum 5000 Light Source, Stryker SE5 Shaver, W.O.M. 20L Insufflator, W.O.M. 2.0L Arthroscopy Pump, Stryker Total Performance System, Berchtold Surgical Lights, Steris Amsco Table Model SP3085, AESOP®HERMES-Ready™, Valleylab Force FX™ Electro-surgical Unit, and Dyonics® Access 15 Arthroscopic Fluid Irrigation System. 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 & thoracoscopic 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 O.R. Control Center are general surgeons,

gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

5) The HERMES O.R. Control Center has been tested to the following standards:

Test	**Comments**
IEC 601-1	International Standard for Medical Electrical Equipment
IEC 601-1 Amendment 1	International Standard for Medical Electrical Equipment
IEC 601-2-18	International Standard for Medical Electrical Equipment
UL 2601-1	Underwriters Laboratory
CAN/CSA-C22.2 No. 601.1	Medical Electrical Equipment Part 1, General Requirements for Safety, General Instructions Part 1
EN55022/A1	Conducted Emission
EN55022/A1	Radiated Emission
EN61000-4-2	Electrostatic Discharge
EN61000-4-3 and EN50140	RF Immunity
EN61000-4-4	EFT/Bursts Immunity
EN61000-4-5	Surge Immunity
EN61000-4-6	Conducted Immunity
EN60601--1	International Standard for Medical Electrical Equipment
EN60601-1-1	General Requirements for Safety –Collateral Standard
EN 60601-1-2	Emissions and Immunity Test Measurements
N/A	System Functional Testing
N/A	Software Verification and Validation
N/A	Environmental Testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

Computer Motion, Inc.
Cathy Stupak, Ph.D.
Regulatory Specialist
130 Cremona Drive, Suite B
Goleta, California 93117

Re: K022897
Trade/Device Name: Modification to Hermes Operating Room Control Center
Regulation Number: 876.1500
Regulation Name: Laparoscope for use in general and plastic surgery
Regulatory Class: Class II
Product Code: GCJ
Dated: October 1, 2002
Received: October 2, 2002

Dear Dr. Stupak:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

INDICATION FOR USE STATEMENT

510(k) Number (if known): K022897

Device Name: HERMES O.R. Control Center

The HERMES™ O.R. Control Center and Port Expander is indicated for use with Stryker Endoscopy 882 Camera, Stryker Quantum 5000 Light Source, Stryker SE5 Shaver, W.O.M. 20L Insufflator, W.O.M. 2.0L Arthroscopy Pump, Stryker Total Performance System, Berchtold Surgical Lights, Steris Amsco Table Model SP3085, AESOP®HERMES-Ready™, Valleylab Force FX™ Electro-surgical Unit, and Dyonics® Access 15 Arthroscopic Fluid Irrigation System. 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 & thoracoscopic 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 O.R. Control Center are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

(PLEASE NO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CRDH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) (Optional Format 1-2-96)

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

510(k) Number K022897