K013804

DEC 1 0 2001

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

SOCRATES Robotic Telemonitoring 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: November 7, 2001

2) Name of Device:

Proprietary Name: SOCRATES™ Robotic Telemonitoring System
Common Name is SOCRATES Robotic Telecollaboration System
Classification Name: Laparoscope for Use in General and Plastic Surgery, Regulation Number 876.1500, Class II.

3) Substantially equivalent to the Computer Motion, Inc. Socrates Robotic Telemonitoring System (K003661)

4) The SOCRATES System is indicated for use in general thoracoscopy, general cardiothoracic surgery, general laparoscopy, nasopharyngoscopy, ear endoscopy, and sinuscopy where a rigid 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. *Use of the SOCRATES System remote controller enables a remote surgeon to telecommunicate with any AESOP HR local controller. This communication link allows the remote surgeon to assist the local surgeon with field-of-view positioning.*

5) The SOCRATES Robotic Telemonitoring System 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

DEC 1 0 2001

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

Re: K013804
Trade Name: Socrates™ Robotic Telemonitoring System
Regulation Number: 876.1500
Regulation Name: Robotic Telemedicine Device
Regulatory Class: II
Product Code: NEQ
Dated: November 14, 2001
Received: November 15, 2001

Dear Mr. Thomas:

We have reviewed your Section 510(k) premarket 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) 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" (21CFR 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,

Susan Walker

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

K013804

510(k) Number (if known): _____

Device Name: SOCRATES™ Robotic Telemonitoring System

Indication For Use:

The SOCRATES System is indicated for use in general thoracoscopy, general cardiothoracic surgery, general laparoscopy, nasopharyngoscopy, ear endoscopy, and sinuscopy where a rigid 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. *Use of the SOCRATES System enables a remote surgeon to telecommunicate with any AESOP HR local controller through HERMES. This communication link allows the remote surgeon to assist the local surgeon with field-of-view positioning.*

The users of the SOCRATES System 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format)

Susan Walker

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

510(k) Number K013804

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