AESOP 3000 System 510(k) Summary

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

DEC 19 1997

K972699

1) Submitter Information

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

2) Name of Device

Proprietary Name: AESOP 3000 System and Accessories
Common Name: Automated Endoscopic System for Optimal Positioning
Classification Name: Laparoscope, General & Plastic Surgery

3) Substantially equivalent to AESOP 510(k)'s K931783, K960655 and K963126.

4) The AESOP 3000 System is a robotic computer-driven system whose basic function is to hold and position a laparoscope/endoscope under the direct control of a surgeon.

The intended use of the AESOP 3000 System is a robotic computer driven system whose function is to hold and position a rigid laparoscope/endoscope . The AESOP 3000 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. The users of the AESOP 3000 System are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

5) The AESOP 3000 System 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
- AMMI TIR 12 Design, Testing, and Labeling Reusable Medical Devices for Reprocessing in Healthcare Facilities
- EMC Directive European Union 89/336/EEC
- CAN/CSA-C22.2 NO. 601.1-M90 & NO. 601.2.18-92
- AESOP 3000 System Functional Test Requirements

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 1997

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

Re: K972699
Trade Name: "AESOP 3000 System and Accessories"
Regulatory Class: II
Product Code: GCJ
Dated: October 21, 1997
Received: October 22, 1997

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.

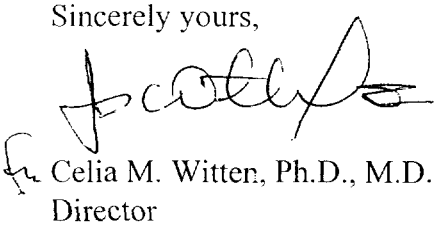
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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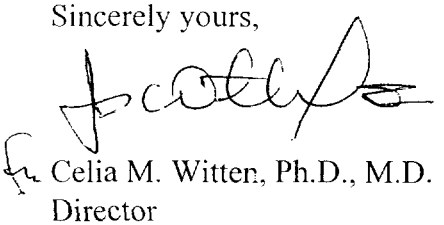

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
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Office of Device Evaluation
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Enclosure

3. Intended Use and Indications for Use

3.1. Intended Use

The AESOP 3000 System is intended to be used as a robotic, computer-driven system whose function is to hold and position a rigid laparoscope/endoscope .

3.2. Indications For Use

The AESOP 3000 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. The users of the AESOP 3000 System are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972699