AESOP System 510(k) Summary

K963126

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

APR - 7 1997

1) Submitter Information

Computer Motion. Inc.
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Contact: Douglas Bueschel
Prepared: August 9, 1996

2) Name of Device

Proprietary Name: AESOP 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 and K960655.

4) The AESOP 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 System is a robotic computer driven system whose function is to hold and position a rigid laparoscope/endoscope . The AESOP 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 System are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

5) The AESOP 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
- UL544 Third Edition
- 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 System Functional Test Requirements