

AESOP 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

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2) Name of Device

Proprietary Name: AESOP System and Accessories
Common Name: Automated Endoscopic System for Optimal Positioning
Classification Name: Operating Room Table and Accessories

3) Substantially equivalent to AESOP 510(k) K931783

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

5) The intended use of the AESOP System is a robotic computer driven system whose function is to hold and position a laparoscope. It is indicated for use in all forms of laparoscopic surgery. A few examples are cholecystectomy, laparoscopic hernia repair, and laparoscopic appendectomy.

6) The AESOP System is comparable to original AESOP System in that it uses the same control methods to position the laparoscope and introduces a new control method of voice control. The control method of voice control is a self-contained speaker dependent speech recognition system. The Voice Control Interface recognizes verbal commands and passes them to the AESOP System to hold and position a laparoscope the same as the Hand or Foot Control of the AESOP System.

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