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NOV 26 1997

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## 510(k) SUMMARY

This document comprises a Summary of Safety and Effectiveness Information for EndoAssist

Date Prepared: August 26th 1997

Submitter: Armstrong Healthcare Ltd.  
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Contact: Patrick Finlay PhD  
Managing Director  
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### B. Device Name

Proprietary name: EndoAssist  
Common or Usual Name: Endoscopic Camera manipulator  
Classification Name: Rigid Endoscope Accessory

### C. Devices to which Substantial Equivalence is being claimed

1. Automated Endoscopic System for Optimal Positioning (AESOP), manufactured and distributed by Computer Motion Inc. (California, USA). 510(k) reference K931783
2. Endex Endoscopy Positioning System, manufactured and distributed by Andronics Devices Ltd. (Canada). 510(k) reference K922626

### D. Device Description

EndoAssist is a microprocessor-driven robotic arm which holds a rigid laparoscope for the surgeon during laparoscopic surgical procedures. It stands separately from the operating table, and reaches up and over into the

surgical field through a series of motorized mechanical linkages. These motors allow the microprocessor to change the configuration of the linkage.

### **E. Intended Use**

EndoAssist is intended to be used as a mechanical laparoscope holder and manipulator for all forms of laparoscopic and thoracoscopic surgery.

### **F. Technological Characteristics**

With the exceptions described below, the technological characteristics of EndoAssist are similar to those of predicate devices.

EndoAssist positions the laparoscope in response to direct commands from the surgeon by means of a headset worn by the surgeon. An indicator box positioned close to the video monitor provides feedback to the surgeon before the command is actioned. AESOP positions the laparoscope in response to foot pedal instructions, and does not provide visual feedback to the surgeon before the command is actioned.

EndoAssist is free-standing whereas AESOP is attached to the operating table side-rail; EndoAssist uses stepper motors to produce movement, AESOP uses DC servo motors.

EndoAssist uses the physical positioning of the device to ensure registration of the axis focal spot, and has the minimum number of motorized axes for the movements required. The geometry of the mechanism ensures that the laparoscope always passes through the focal spot. AESOP uses a software algorithm to achieve registration. The geometry of AESOP does not automatically ensure that motion passes through a focal point. Instead AESOP uses additional motorized axes and a software algorithm to ensure this.

### **G. Method of Determination of Substantial Equivalence**

The determination of substantial equivalence is not based on an assessment of clinical performance data.

EndoAssist has the same intended use, and is as safe and effective, as the Computer Motion device "AESOP" and other mechanical laparoscope holders. EndoAssist does not raise different questions of safety and effectiveness because it is an incremental improvement of predicate devices which achieves equivalent diagnostic results through modifications based on existing technology.

### **H. Safety Issues**

EndoAssist was designed to address safety concerns at a number of levels:

The area of operational safety was addressed by designing a simple and intuitive user interface. All commands are given in reference to the image seen on the video monitor. For example, to cause the video image to pan to the left, the surgeon looks to the left of the video image, sees a left-pointing arrow on the indicator box, and presses a footswitch to action the movement.

At the electrical level, EndoAssist uses stepper motors to produce movement, thereby ensuring that in the event of an error condition, movement of the laparoscope stops.

At the mechanical level, safety is achieved by incorporating force limitations and a quick release mechanism such that the device cannot exert significant force on the patient.

Additionally, EndoAssist monitors itself electronically and by extensive and continuous error-checking in the firmware. Finally, there is electronic redundancy in the hardware of all important safety-related components, so that EndoAssist is fail-safe.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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NOV 26 1997

Re: K973249  
Trade Name: Endoassist  
Regulatory Class: II  
Product Code: GCJ  
Dated: August 26, 1997  
Received: August 29, 1997

Dear Dr. Finlay:

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.

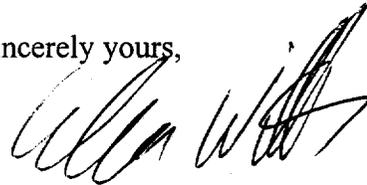
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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  
Radiological Health

Enclosure

510(k) Number (if known): premarket notification K973249

Device Name ENDOC ASSIST

Indications For Use:

Endo Assist positions a laparoscope, and is indicated for use in laparoscopic, thoracoscopic and pelvic procedures including

- Laparoscopic: cholecystectomy
- hernia repair
- fundoplication
- splenectomy
- appendectomy
- hemicolecotomy
- sympathectomy
- lymph node dissection
- hysterectomy
- hysteroscopy

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K 97 3249

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)