



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Val Med Corporation  
% Mr. Howard M. Holstein, Esq.  
Hogan & Hartson L.L.P.  
555 Thirteenth Street, N.W.  
Columbia Square  
Washington, D.C. 20004

JUL 27 2015

Re: K010754  
Trade/Device Name: Val Med Corporation Nurse's Assistant O.R. Control System  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: GCJ, FET, FSY, HET, HIF, GEI and LMC  
Dated (Date on orig SE ltr): July 5, 2001  
Received (Date on orig SE ltr): July 5, 2001

Dear Mr. Holstein,

This letter corrects our substantially equivalent letter of August 15, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Benjamin R. Fisher -S**

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K010754

Device Name: Val Med Corp. Nurse's Assistant O.R. Control System

Indications for Use:

The Nurse's Assistant is intended to be used to turn on and off and adjust certain settings of endoscopic and surgical cameras, surgical lamps, and operating room ("O.R.") lights, and to operate VCRs, monitors, video printers, radios, and CD players.

The Val Med Nurse's Assistant is indicated for use in general, cardiovascular, ENT, gastroenterology, urology, plastic, obstetrics, gynecology, and orthopedic surgery, and general thorascoscopy, general cardiothoracic surgery, general laparoscopy, nasopharyngoscopy, ear endoscopy, and sinuscopy. A few examples of the more common surgical procedures where this system could be used are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic and thorascopic anteriorspinal 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, examination of the evacuated cardiac chamber during performance of valve replacement, arthroscopic meniscus repair, anterior cruciate ligament repair and associated procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  (Per 21 C.F.R. 801.109)

Over-The-Counter Use

*Mark A. Miller*  
(Division Sign-Off)

(Optional Format 1-2-96)

Division of General, Restorative and Neurological Devices

510(k) Number K010754

K010754

**AUG 1 5 2001**

**510(k) SUMMARY**

**Val Med's Nurse's Assistant O.R. Control System**

**Submitter's Name, Address, Telephone Number, Contact Person  
and Date Prepared**

Val Med Corp.  
4800 NW Saltzman Road  
Portland, Oregon 97229  
Telephone: (503) 614-1106  
Facsimile: (503) 614-1109

Contact Person: Darko Spoljaric  
Vice President

Date Prepared: March 13, 2001

**Name of Device and Name/Address of Sponsor**

Val Med Corp.  
4800 NW Saltzman Road  
Portland, Oregon 97229  
Telephone: (503) 614-1106  
Facsimile: (503) 614-1109

**Common or Usual Name**

Surgical Control Center

**Classification Name**

Accessory to a Ceiling Mounted Surgical Lamp  
Accessory to a Medical Image Storage Device  
Accessory to a Laparoscope, General & Plastic Surgery

**Predicate Devices**

Computer Motion's Hermes Operating Room Control Center  
Olympus EndoAlpha  
Karl Storz KSEA SCB-RUI  
Hill-Rom, Inc.'s BrightStar©  
American Sterilizer Co.'s Quantum©, SQ24

Getinge/Castle, Inc. OptiView©, 500 series

### **Intended Use / Indications for Use**

The Val Med Nurse's Assistant is intended to be used to turn on and off and adjust certain settings of endoscopic and surgical cameras, surgical lamps, and operating room ("O.R.") lights, and to operate VCRs, monitors, video printers, radios, and CD players.

The Val Med Nurse's Assistant is indicated for use in general, cardiovascular, ENT, gastroenterology, urology, plastic, obstetrics, gynecology, and orthopedic surgery, and general thorascoscopy, general cardiothoracic surgery, general laparoscopy, nasopharyngoscopy, ear endoscopy, and sinuscopy. A few examples of the more common surgical procedures where this system could be used are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic and thorascopic anteriorspinal 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, examination of the evacuated cardiac chamber during performance of valve replacement, arthroscopic meniscus repair, anterior cruciate ligament repair and associated procedures.

### **Performance Data**

The Nurse's Assistant's control unit meets EN 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety 4: Collateral Standard: Programmable Electrical Medical Systems.

The Nurse's Assistant's power supply meets UL 2601-1 "U.L. Standard for Safety for Medical Electrical Equipment – General Requirements for Safety".

The Nurse's Assistant's controlling software meets ANSI standard 1375-221.

### **Technological Characteristics**

The Val Med's Nurse's Assistant is a computer with a monitor and touch screen that a nurse uses in the operating room to activate and control the following equipment: (1) surgical cameras, including an endoscopic camera;

(2) room or surgeons'/nurses' lounge cameras ("operating room cameras");<sup>1</sup> (3) surgical lights; (4) room lights; (5) a VCR;<sup>2</sup> (6) a video printer; (7) video monitor(s);<sup>3</sup> (8) a radio; and (9) a CD player.<sup>4</sup> Val Med's Nurse's Assistant controls one or more electrical dimmer switches, which in turn control the surgical lights.

### **Substantial Equivalence**

The Nurse's Assistant has the same intended use and similar indications for use and technological characteristics as its predicate, Computer Motion's Hermes Operating Room Control Center, the Olympus EndoAlpha, and the Storz KSEA SCB-RUI. In addition, the surgical lamp that is used with the Nurse's Assistant is substantially equivalent to Hill-Rom, Inc.'s BrightStar©, American Sterilizer Co.'s Quantum©, SQ240, and Getinge/Castle, Inc. OptiView©, 500 series. Therefore, the Nurse's Assistant is substantially equivalent to its predicate devices.

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<sup>1</sup> We believe that these surgical cameras are Class I exempt devices, under 21 C.F.R. § 878.4160.

<sup>2</sup> We believe that the VCR is a medical image storing device under 21 C.F.R. § 892.2010(a), which is, therefore, a Class I exempt storage device. Alternatively, it is not a medical device, subject to FDA regulation.

<sup>3</sup> We believe that these monitors are accessories to medical image communications devices. As such, these monitors are Class I exempt from 510(k) requirements under 21 C.F.R. § 892.2020(a), which states that a "medical image communications device" provides "electronic transfer of medical images between medical devices."

<sup>4</sup> We have not been able to identify any device classification regulations that encompass operating room lights, operating room cameras, speakerphones, radios, and CD players nor have we identified any cleared devices like these products. For this reason, we believe that these products are not medical devices and the company will not make medical claims related to these components.