



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

Siemens Medical Corporation  
Ms. Malgorzata Stanek, RAC  
Senior Technical Specialist  
186 Wood Avenue South  
Iselin, NJ 08830

JUL 27 2015

Re: K994231  
Trade/Device Name: Siemens Integrated Operating System (SIOS)  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: ODA  
Dated (Date on orig SE ltr): May 30, 2000  
Received (Date on orig SE ltr): May 31, 2000

Dear Ms. Stanek,

This letter corrects our substantially equivalent letter of August 10, 2000.

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

**ATTACHMENT 8**

**INDICATIONS FOR USE**

510(k) Number (if known): K994231  
Device Name: Siemens Integrated Operating System (SIOS)

**Indications For Use:**

The SIOS product is intended to optimize procedures in the operating room by providing consistent pre-operative, intra-operative and post-operative equipment control, image and data handling, and networking capabilities.

The SIOS product is limited to use with the following products:

- (1) Wolf Endocam - 3CCD Endocam 5507,
- (2) Wolf Light Source - Auto-CP 5131,
- (3) Wolf Insufflator - Laparo CO<sub>2</sub> Pacu 2332, and
- (4) Maquet OR Table - ALPHAMAQUET 1150.

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Denise R. Lockner.  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K994231

Prescription Use  OR Over-The-Counter Use   
(Per 21 CFR 801.109)

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K994231

ATTACHMENT 7

510(k) SUMMARY

FOR THE  
SIEMENS INTEGRATED OPERATING SYSTEM (SIOS)

Submitted by:

Siemens Medical Systems, Inc.  
186 Wood Avenue South  
Iselin, NJ 08830

December 15, 1999

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Contact Person:**

Ms. Malgorzata Stanek  
Phone: (732) 321-3950 Fax: (732) 321-4841

2. **Device Name and Classification:**

Trade Name: Siemens Integrated Operating System (SIOS)  
Classification Name: Endoscope and/or Accessories  
Classification Panel: General Surgery  
CFR Section: 21 CFR § 876.1500  
Device Class: Class II  
Product Code: 78KOG

3. **Substantial Equivalence:**

The Siemens Integrated Operating System is designed to control select medical equipment in the operating room (OR), allow trained medical personnel direct control of the equipment using remote control (i.e., verbal commands, hand input device), and network with hospital information systems (HIS) and picture archival communication systems (PACS).

The package is substantially equivalent to the following devices:

Device Name	Manufacturer	FDA 510(k) Number	FDA Clearance Date
HERMES™ Operating Room Control Center and Accessories	Computer Motion	K980787	7/31/98
EndoALPHA™ Integrated Endosurgery System	Olympus	K981993	8/21/98

K994231

**4. Device Description:**

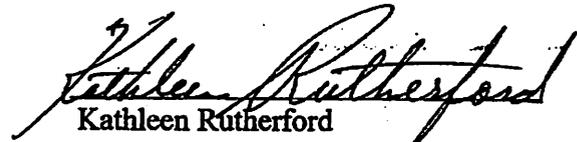
The Siemens Integrated Operating System (SIOS) is a system capable of networking select medical and non-medical equipment in the operating room (OR) and allowing trained medical personnel direct control of the equipment using remote control (i.e. voice command, touch screen console). The device combines a number of individual functional units through a standard interface to a centralized computer control station.

**5. Intended Use of the Device:**

The SIOS product is intended to optimize procedures in the operating room by providing consistent pre-operative, intra-operative and post-operative equipment control, image and data handling, and networking capabilities.

**6. Summary of Technological Characteristics of the Devices Compared to the Predicate:**

The SIOS product is substantially equivalent to HERMES™ by Computer Motion and EndoALPHA™ by OLYMPUS. All systems enable remote control of connected devices without changing the original functionality of those devices.

  
Kathleen Rutherford  
Manager, Regulatory Submissions  
Siemens Medical Systems, Inc.