DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

ConMed Integrated Systems
Mr. C. Jeff Lipps
Director, Regulatory Affairs
and Quality Assurance
1815 NW 169th Place, Suite 4020
Beaverton, OR 97006

JUL 27 2015

Re: K091648
Trade/Device Name: Nurse's Assistant® O.R. Control System, 1.8
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ, OCS
Dated (Date on orig SE ltr): July 22, 2009
Received (Date on orig SE ltr): July 28, 2009

Dear Mr. Lipps,

This letter corrects our substantially equivalent letter of August 5, 2009.

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

K091648

INTENDED USE / INDICATIONS FOR USE

510(K) #: K091648

Device Name: Nurse's Assistant® O.R. Control System, 1.8

Intended Use /Indications for Use:

The Nurse's Assistant® O.R. Control System, 1.8 is a programmable electrical medical system that is intended to provide trained staff with a centralized user interface from which to route audio and video signals, and to perform auxiliary control functions for activating, adjusting and monitoring certain settings of compatible medical and non-medical equipment.

The Nurse's Assistant® O.R. Control System, 1.8 is indicated for use in an operating room for video assisted surgery during minimally invasive and traditional open procedures in all surgical specialties. The System is also used as an adjunct display of interventional techniques and provides teleconferencing capability through an optional interface.

Prescription Use ____X____ (Part 21 CFR 801.109 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091648

K091648

AUG 05 2009

Nurse's Assistant® O.R. Control System, 1.8 22 July 2009
510(k) #: K091648

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Integrated Systems is hereby submitting the 510(k) Summary of Safety and Effectiveness for the Nurse's Assistant® O.R. Control System, 1.8.

A. Manufacturer:

ConMed Integrated Systems
1815 NW 169th Place, Suite 4020
Beaverton, OR, USA 97006
FDA Establishment Registration Number: 3031835

B. Company Contact:

C. Jeff Lipps
Director of Regulatory Affairs and Quality Assurance
503-614-1106 Phone
503-614-1109 Fax

C. Device Name:

Trade Name:	Nurse's Assistant® O.R. Control System, 1.8 Nurse's Assistant® System 1.8
Common Name:	Surgical Control Center
Classification Names:	876.1500 – Endoscope and accessories
Proposed Class/Device:	Class II
Product Codes:	GCJ, KOG

D. Predicate/Legally Marketed Devices:

1. ConMed Integrated Systems Nurse's Assistant® 1.7 O.R. Control System – K060717
2. Stryker SwitchPoint Infinity System – K033132
3. Karl Storz OR1 SCB Interface Control – K070827

E. Device Description:

The Nurse's Assistant® O.R. Control System, 1.8, is a modification of an existing device that is composed of off-the-shelf audio/video hardware components, proprietary software that runs on a non-Windows based operating system and a touch panel interface with an intuitive graphical user interface. The Nurse's Assistant® System 1.8 communicates with interconnected devices through standard data communication protocols which allows the adjustment of equipment settings and routing of audio/video signals from one location in the operating room.

Intended Use:

The Nurse's Assistant® O.R. Control System, 1.8, is a programmable electrical medical system that is intended to provide trained staff with a centralized user interface from which to route audio and video signals, and to perform auxiliary control functions for activating, adjusting and monitoring certain settings of compatible medical and non-medical equipment.

Indications for Use:

The Nurse's Assistant® O.R. Control System, 1.8, is indicated for use in an operating room for video assisted surgery during minimally invasive and traditional open procedures in all surgical specialties. The System is also used as an adjunct display of interventional techniques and provides teleconferencing capability through an optional interface.

F. Device Technological Characteristics to Predicate Devices:

The Nurse's Assistant® O.R. Control System, 1.8, has the same intended use and technological characteristics as the predicate devices.

G. Performance Standards, Voluntary Standards, Clinical Testing:

There are no applicable mandatory performance standards established for this type of device. The Nurse's Assistant® O.R. Control System, 1.8, complies with UL 60601-1, 1st Edition and EN 60601-1-2 and additional voluntary consensus standards detailed in the submission. Clinical testing is not required for this device.

H. Conclusion:

The technological differences between the Nurse's Assistant® O.R. Control System, 1.8, the Nurse's Assistant® 1.7 O.R. Control System, Stryker Switchpoint Infinity and Karl Storz OR1 SCB Interface Control raise no new concerns for safety or efficacy. The Nurse's Assistant® O.R. Control System, 1.8 is substantially equivalent to the identified predicate devices.