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 a Special 510(k) Summary of Safety and Effectiveness for the Nurse's Assistant® 1.7B O.R. Control System.

A. Submitter:

ConMed Integrated Systems
Registration Number: 3031835

B. Company Contact:

C. Jeff Lipps
Director of Regulatory Affairs and Quality Assurance
1815 NW 169th Place, Suite 4020
Beaverton, OR 97006
503-614-1106 Phone
503-614-1109 Fax

C. Device Name:

Proprietary Name:	Nurse's Assistant® 1.7 O.R. Control System
Trade Name:	Nurse's Assistant® 1.7
Common Name:	Surgical Control Center
Classification Names:	876.1500 – Endoscope and accessories
Proposed Class/Device:	Class II
Product Codes:	GCJ

D. Predicate/Legally Marketed Devices:

1. ConMed Integrated Systems Nurse's Assistant 1.7 O.R. Control System – K050829
2. Computer Motion, Inc. HERMES O.R. Control Center – K030240

E. Intended Use / Indications for Use:

The Nurse's Assistant® 1.7 O.R. Control System is a computerized control system that is intended to provide operating room (OR) staff with a simple, centralized user interface from which to activate, adjust and monitor certain settings of equipment located in the OR and to route video from multiple sources to multiple destinations.

The Nurse's Assistant® 1.7 O.R. Control System is indicated for use in an operating room for video assisted surgery. This includes minimally invasive procedures in all surgical specialties, as an adjunct display of interventional techniques and traditional open procedures.

The Nurse's Assistant® 1.7 O.R. Control System indicated for use with ConMed Linvatec IM3300 Endoscopic Camera, ConMed Linvatec LS7500 Xenon Light Source, ConMed Linvatec GS1002 40L Insufflator, ConMed Electrosurgery System 5000 Electrosurgery Unit (ESU), ConMed Linvatec VP-1500 Digital Capture Device, Getinge ALM Surgical Lamp Energix WPS, Getinge ALM PrismaVision PRV3 Surgical Light Camera, Berchtold Chromophare D-Series Surgical Lamps, Berchtold ChromoVision HR24 Surgical Light Camera, National Display Systems 15" & 18" Vector III and 19" Radiance flat panel displays, Sony LMD-2140MD 21" flat panel display, Sony UP-51MD or Sony UP-51MDU video printers, Sony SVO-9500MD VCR, and ProVation™ procedure documentation device.

The Nurse's Assistant® 1.7 O.R. Control System is indicated for use in general, cardiovascular, ENT, gastroenterology, urology, plastic, obstetrics, gynecology, and orthopedic surgery, and general thoracoscopy, general cardiothoracic surgery, general laparoscopy, arthroscopy, laparoscopy, nasopharyngoscopy, ear endoscopy and sinusoscopy.

F. Substantial Equivalence / Device Technological Characteristics and Comparison to Predicate Device(s):

The Modification to Nurse's Assistant® 1.7 O.R. Control System has the same intended use and similar indications for use as the predicate device ConMed Integrated Systems Nurse's Assistant 1.7 O.R. Control System (K050829) and Computer Motion's HERMES O.R. Control Center (K030240)..

The technological characteristics of the Modification to Nurse's Assistant® 1.7 O.R. Control System are equivalent to the predicate devices listed above.

Tests performed on the Modification to Nurse's Assistant® 1.7 O.R. Control System demonstrate substantial equivalence to the predicate devices listed above.

The Modification to Nurse's Assistant® 1.7 O.R. Control System is substantially equivalent to the predicate devices in terms of safety, effectiveness, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2005

C. Jeff Lipps
Director, RA/QA
ConMed Integrated Systems
1815 NW 169th Place, Suite 4020
Beaverton, Oregon 97006

Re: K052740
Trade/Device Name: Modification to Nurse's Assistant® 1.7 O.R. Control System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: September 29, 2005
Received: September 30, 2005

Dear Mr. Lipps:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) # (if known): K052740

Device Name: Modification to Nurse's Assistant® 1.7 O.R. Control System

Indications for Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 General, Restorative, and Neurological Devices

510(k) Number K052740