K083161

ConMED LINVATEC
11311 Concept Boulevard • Largo, FL 33773-4908 • 727-392-6464 • www.linvatec.com

510(k) SUMMARY
ConMed Linvatec Zen™ Wireless Footswitch and Adapter

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Linvatec is hereby submitting the 510(k) Summary of Safety and Effectiveness for the 510(k) Number _____.

MAR 2 7 2009

A. Submitter

ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

B. Company Contact

Sue F. Dauterman
Regulatory Affairs Manager
(727) 399-5321 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name: *ConMed Linvatec Zen™ Wireless Footswitch and Adapter*

Common Name: Wireless Footswitch

Classification Name: Arthroscope, 888.1100

Proposed Class/Device: Class II

Product Code: HRX

D. Predicate/Legally Marketed Devices

ConMed Linvatec 3-Pedal	510(k) # K990524	ConMed Linvatec Footswitch
Stryker Wireless Universal	510(k) # K033135	Stryker Endoscopy Footswitch System
IR Wireless Footswitch System	510(k) # K053510	Linemaster Switch Corporation

P. 1/2

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E. Device Description

The *ConMed Linvatec Zen™ Wireless Footswitch and Adapter* consists of a Wireless Footswitch (W1000) and a Wireless Footswitch Adapter (W1100) used for control of handpieces connected to a compatible ConMed Linvatec drive console. The Wireless Footswitch is designed to receive a communication signal from the Wireless Footswitch Adapter and, when a footswitch pedal is depressed, activate the drive console accordingly to power a ConMed Linvatec handpiece.

F. Intended Use

The *ConMed Linvatec Zen™ Wireless Footswitch and Adapter* is an accessory that is intended to interface with compatible ConMed Linvatec power drive consoles to selectively control ConMed Linvatec surgical instruments.

G. Substantial Equivalence

The *ConMed Linvatec Zen™ Wireless Footswitch and Adapter* is substantially equivalent in intended use and design characteristics to the ConMed Linvatec 3-Pedal Footswitch.

The *ConMed Linvatec Zen™ Wireless Footswitch and Adapter* is substantially equivalent in technological characteristics to the Stryker Wireless Universal Footswitch System (Stryker Endoscopy), and IR Wireless Footswitch System (Linemaster Switch Corporation).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2009

ConMed Linvatec
% Ms. Sue Dauterman
Regulatory Affairs Manager
11311 Concept Boulevard
Largo, Florida 33773-4908

Re: K083161
Trade/Device Name: ConMed Linvatec Zen™ Wireless Footswitch and Adapter
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: March 10, 2009
Received: March 11, 2009

Dear Ms. Dauterman:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

510(k) Number (if known): K083161

Device Name: *ConMed Linvatec Zen™ Wireless Footswitch and Adapter*

Indications for Use:

The *ConMed Linvatec Zen™ Wireless Footswitch and Adapter* is an accessory that is intended to interface with compatible ConMed Linvatec power drive consoles to selectively control ConMed Linvatec surgical instruments.

Prescription Use X 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)

David Krause for MXM 3/27/09

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083161