K063326

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

January 4, 2007

JAN 31 2007

510(k) SUMMARY
ConMed Linvatec 24k Irrigation System

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_____ .

A. Submitter

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

B. Company Contact

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

C. Device Name

Trade Name:	*ConMed Linvatec 24k Irrigation System*
Common Name:	Irrigation System
Classification Name:	Arthroscope, 888.1100
Proposed Class/Device:	Class II
Product Code:	HRX

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510(k) Summary
24k Irrigation System
January 4, 2007

D. Predicate/Legally Marketed Devices

10k Irrigation System Linvatec Corporation	510(k) # K033573
3M Fluid Irrigation System Linvatec Corporation (acquired from 3M Healthcare)	510(k) #K941388
Nextra Arthroscopic Pump and Shaver System Future Medical Systems, Inc.	510(k) #K954465
Arthroscopy Pump, Model A107 W.O.M. World of Medicine, Ag Marketed by Stryker Endoscopy as FloControl	510(k) #K030402
Hall Irrigation System Linvatec Corporation (acquired from Hall Surgical)	510(k) # K852143
HydroFlex LI Laparoscopic Irrigation System Davol, Inc.	510(k) # K961224

E. Device Description

The *ConMed Linvatec 24k Irrigation System* is a peristaltic pump system designed to automatically provide and control distention and irrigation of the operative site during arthroscopic procedures and fluid irrigation of the operative site during laparoscopic procedures using sterile fluids. The pump is used in conjunction with specific tubing sets designed for either arthroscopic or laparoscopic procedures.

F. Intended Use

The *ConMed Linvatec 24k Irrigation System* is a dual-head pump system intended to provide fluid distention, irrigation, and suction during diagnostic and operative knee, shoulder, hip, and small bone arthroscopic procedures and fluid irrigation during laparoscopic procedures.

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G. Substantial Equivalence

The *ConMed Linvatec 24k Irrigation System* is substantially equivalent in intended use, design and technological characteristics to the 10k Irrigation System (Linvatec Corporation), 3M Fluid Irrigation System (Linvatec Corporation), Nextra Arthroscopic Pump and Shaver System (Future Medical Systems, Inc.), Arthroscopy Pump, Model A107 (W.O.M. World of Medicine, Ag), HydroFlex LI Laparoscopic Irrigation System (Davol, Inc.) and Hall Irrigation System (Linvatec Corporation). Testing conducted prior to product release will assure the new device does not raise any new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JAN 31 2007

Re: K063326
Trade/Device Name: *ConMed Linvatec 24k Irrigation System*
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: January 4, 2007
Received: January 9, 2007

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 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 (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

K063326

CONMED LINVATEC
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October 16, 2006

510(k) Number (if known):

Device Name: *ConMed Linvatec 24k Irrigation System*

Indications for Use:

The *ConMed Linvatec 24k Irrigation System* is a dual-head pump system intended to provide fluid distention, irrigation, and suction during diagnostic and operative knee, shoulder, hip, and small bone arthroscopic procedures and fluid irrigation during laparoscopic procedures.

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)

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

510(k) Number K063326