



Food and Drug Administration
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ConMed® Corporation
ConMed® Endoscopic Technologies, Inc.
Thomas Hirte, P.E.
Senior Regulatory Affairs Specialist
129 Concord Road, Building 3
Billerica, MA 01821

JUL 27 2015

Re: K050304
Trade/Device Name: FXWire™ Advanced Measurement Guidewire
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCY
Dated (Date on orig SE ltr): February 3, 2005
Received (Date on orig SE ltr): February 8, 2005

Dear Mr. Hirte,

This letter corrects our substantially equivalent letter of March 8, 2005.

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

Indications for Use Statement

510(k) Number (if known): TBD K050304

Device Name: FXWire™ Advanced Measurement Guidewire

Indications For Use: To be used to guide and exchange endoscopic accessories and electrosurgical devices for biliary procedures. The guidewire is indicated for selective cannulation of the biliary ducts, including but not limited to the common bile, cystic, pancreatic, and right and left hepatic ducts.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

David H. Ferguson

(Division Sign-Off)
Division of General
and Radiological Devices
510(k) Number K050304

K050304
P/F 1/2

MAR 8 - 2005



**510(k) SUMMARY OF
SAFETY AND EFFECTIVENESS INFORMATION**

- A. **Submitter Information:**
Submitter's Name: ConMed Endoscopic Technologies, Inc.

Submitter's Address: 129 Concord Road,
Billerica MA 01821-7031

Contact Person: Thomas Hirte

Contact Person's Telephone Number: (978) 964-4252

Contact Person's FAX Number: (978) 964-4250

B. **Device Name:**
FXWire™ Advanced Measurement Guidewire

C. **Predicate Devices:**
XWire™ Next Generation Guidewire (K011759)

D. **Device Description:**

The FXWire™ Advanced Measurement Guidewire is a kink resistant metal alloy cored guidewire, which is encapsulated in a PTFE jacket. The guidewire has a flexible radiopaque tip, with a hydrophilic coating for enhanced lubricity. At the distal end of the guidewire, there are painted marker bands beginning at 6cm and extending to 30cm from the distal tip of the guidewire, as well as two radiopaque marker bands placed at 10cm and 15 cm from the distal tip of the guidewire. Additionally, at the proximal end of the guidewire, endoscopic marker bands have been placed beginning at 210cm and extending to 270cm from the distal tip of the guidewire. These marker bands enable endoscopic and fluoroscopic visualization of movement, as well as estimation of stricture length. This guidewire meets the recognized standard for high frequency current leakage (Reference ANSI/AAMI

Standard HF 18-1993) when used with a sphinctertome and may be left in place during electrosurgical cutting.

E. Intended Use:

The FXWire Advanced Measurement Guidewire is designed to be used to guide and exchange endoscopic accessories and electrosurgical devices for biliary procedures.

F. Technological Characteristics Summary:

The FXWire™ Advanced Measurement Guidewire device is a kink resistant metal alloy cored guidewire, which is encapsulated in a PTFE jacket. The guidewire has a flexible radiopaque tip, with a hydrophilic coating. At the distal end of the guidewire, there are painted marker bands beginning at 6cm and extending to 30cm from the distal tip of the guidewire, as well as two radiopaque marker bands placed at 10cm and 15 cm from the distal tip of the guidewire. Additionally, at the proximal end of the guidewire, endoscopic marker bands have been placed beginning at 210cm and extending to 270cm from the distal tip of the guidewire.

G. Performance Data:

Design verification data demonstrated that the FXWire™ Advanced Measurement Guidewire meets the same performance requirements and is as safe and effective as the predicate device.