

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

As required by the Safe Medical Devices Act of 1990, codified under Section 513, Part (i)(3)(A) of the Food Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based follows.

**A. Submitter Information**

Submitter's Name: ConMed Endoscopic Technologies, Inc.  
ConMed Corp.

Address: 129 Concord Road, Bldg. #3  
Billerica, MA 01821

Phone: (978) 964-4253

Fax: (978) 964-4250

Contact Person: Michael A. Patz

Date of Preparation: March 24, 2005

**B. Device Name**

Trade Name: ProForma™ HF 4.5 Cannula

Common/Usual Name: Dilator, Esophageal, Biliary

Classification Name: Biliary Catheter/Accessories, Esophageal Dilator

**C. Predicate Device Name(s)**

Trade Name: ProForma™ Cannula

D. Device Description:

The ProForma™ HF 4.5 Cannula is used for endoscopic cannulation of the biliary ductal system. With a tapered, atraumatic tip, and high flow injection port, this device provides cannulation of the papilla and access into the biliary system. The 4.5 French tip accepts a 0.035" (0.889 mm) guidewire. The unique multi-lumen port design at the proximal end, allows for injection of contrast medium through two lumens with a separate port for guidewire passage.

Colored visual markers located on the distal tip endoscopically aid in the assessment of cannulation and insertion into the biliary system. A distal radiopaque marker band aids in fluoroscopic visualization. A proximal marker band indicates when the catheter exists the duodenoscope.

E. Intended Use:

The ProForma™ HF 4.5 Cannula is used for "Cannulation of the Papilla of Vater to deliver contrast medium for fluoroscopic visualization of the biliary/pancreatic system.

F. Technological Characteristics Summary:

The ProForma™ HF 4.5 Cannulas are comprised of the similar medical grade plastics, inks and radiopaque material as the current device.

G. Performance Data:

Functionality, biocompatibility and ship testing were completed and demonstrated that the modified ProForma™ HF 4.5 Cannula is substantially equivalent to the current ProForma™ Cannula and that the device is safe for its intended use and patient population.



APR 22 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Michael A. Patz  
Sr. Regulatory Affairs Specialist  
ConMed® Endoscopic Technologies, Inc.  
ConMed® Corporation  
129 Concord Road, Building #3  
BILLERICA MA 01821

Re: K050777  
Trade/Device Name: Proforma™ HF 4.5 Cannula  
Regulation Number: 21 CFR §876.5010  
Regulation Name: Biliary catheter and accessories  
Regulatory Class: II  
Product Code: FGE  
Dated: March 24, 2005  
Received: March 28, 2005

Dear Mr. Patz:

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 (Premarket Approval), 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.

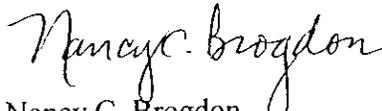
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/dsma/dsmamain.html>

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number (if known): TBD K050777

Device Name: ProForma™ HF 4.5 Cannula

Indications For Use: Cannulation of the Papilla of Vater to deliver contrast medium for fluoroscopic visualization of the biliary/pancreatic system.

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

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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 R. Szymanski  
(Division Sign-Off)  
Division of Reproductive, Abdominal, and  
Radiological Devices  
510(k) Number K050777