



Food and Drug Administration
10903 New Hampshire Avenue
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JUL 27 2015

Terumo Corp.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K091417
Trade/Device Name: Single Use Guidewire G-240-2527S, G-240-2545S, G-240-2527A,
G-240-2545A, G-240-3527S, G-240-3545S, G-240-3527A, G-240-3545A
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCY
Dated (Date on orig SE ltr): May 12, 2009
Received (Date on orig SE ltr): May 13, 2009

Dear Mr. Job

This letter corrects our substantially equivalent letter of May 22, 2009.

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

510(k) Number (if known): K091417

Device Name: Single Use Guidewire G-240-2527S, G-240-2545S, G-240-2527A, G-240-2545A, G-240-3527S, G-240-3545S, G-240-3527A, G-240-3545A

Intended Use

The instrument has been designed to be used with Olympus endo-therapy accessories. The instrument is used for guiding and exchanging endoscopic accessories for biliary duct, including but not limited to the common bile, cystic, pancreatic and right and left hepatic ducts.

Indications for use

This instrument has been designed to be used with Olympus Endo-therapy Accessories. The instrument is used as guidewire of endoscopic accessories for biliary duct including not only common bile but cystic, pancreatic right and left hepatic duct.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 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 Reproductive, Abdominal,
and Radiological Devices

510(k) Number K091417

Terumo Corporation
Premarket Notification – Single Use Guidewire
Section II. 510(k) Summary

SECTION II. 510(K) SUMMARY

MAY 22 2009

A. Device Name

Proprietary Name: Single Use Guidewire
Classification Name: Endoscope and/or accessories
Common Name: Endoscopic Guidewire

B. Intended Use

The instrument has been designed to be used with Olympus endo-therapy accessories. The instrument is used for guiding and exchanging endoscopic accessories for biliary duct, including but not limited to the common bile, cystic, pancreatic and right and left hepatic ducts.

Indications for use

This instrument has been designed to be used with Olympus Endo-therapy Accessories. The instrument is used as guidewire of endoscopic accessories for biliary duct including not only common bile but cystic, pancreatic right and left hepatic duct.

C. Device Description

The Single Use Guidewire consists of a Nickel Titanium alloy core wire with a gold coil and hydrophilic, PTFE and silicone coatings. The distal portion of the wire has been specially processed, which includes thinning, to increase the flexibility. This wire has been designed to be used with the Olympus Endo-therapy Accessories.

D. Principle of Operation / Technology

The Single Use Guidewire is operated manually or by a manual process.

E. Design / Materials

The Single Use Guidewire uses similar materials as the predicate device. Differences in materials between the devices do not raise any new issues of safety and effectiveness.

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F. Performance

The performance of the Single Use Guidewire is substantially equivalent to the performance of the predicate device. The equivalence was shown through bench testing.

G. Additional Safety Information

Manufacturing controls include visual, functional, dimensional and sterility tests.

Blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing".

The wire is classified as Externally Communicating Devices, Tissue/ bone/ dentin communicating, limited Contact (≤ 24 hrs). Results of the testing demonstrate that the blood contacting materials are biocompatible.

Sterilization conditions have been validated in accordance with ANSI/AMMI/ISO 11135-1, Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of sterilization process for medical devices. The device is sterilized to a SAL of 10^{-6} .

H. Substantial Equivalence

The Single Use Guidewire submitted in this 510(k) is substantially equivalent¹ in intended use, design, principle of operation / technology, materials and performance to the LinearGuide, which are manufactured by Olympus and cleared under K021179. Differences between the devices do not raise any issues of safety or effectiveness.

¹ A statement of substantial equivalence to another product is required by 21CFR807.87, and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent, and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the Commissioner of the FDA has stated, "...a determination of substantial equivalence under the federal Food, Drug, and Cosmetic Act relates to the fact that the product can lawfully be marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatever on the resolution of patent infringement suits" 42 Fed. Reg. 42,520, et seq. (1977)

Terumo Corporation
Premarket Notification – Single Use Guidewire
Section II. 510(k) Summary

I. Submitter Information

Prepared By: Mr. Mark Unterreiner
Sr. Regulatory Affairs Specialist

Prepared For: Terumo Medical Corporation
950 Elkton Blvd.
Elkton, MD 21921
Phone: (410) 392-7213
Fax: (410) 398-6079
Email: mark.unterreiner@terumomedical.com

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