510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807, Section 807.92(c).

MAR 1 6 2010

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Date Prepared: July 30, 2009

Device Information

Trade Name: SCUBA™ Biliary Stent System
Common Name: Biliary Stent
Classification Name: Diagnostic Biliary Catheter
(21 CFR 876.5010, Product Code FGE)
Classification: II

Predicate Devices

- Cordis PALMAZ® GENESIS™ Transhepatic Biliary Stent on OPTA™ PRO .035" Delivery System (K012590, K033394)
- Medtronic RACER Biliary Stent System (K032768)

Device Description

The SCUBA Biliary Stent System consists of a balloon-expandable MP35N (cobalt, nickel, chromium molybdenum alloy) stent mounted on a 5 F over-the-wire (OTW) balloon catheter. The stent is provided in nominal expanded diameters of 5 mm to 10 mm, and stent lengths of 18 to 75 mm. The SCUBA Biliary Stent System has an 80 cm usable length and is compatible with 6 or 7 F introducer sheaths, and guidewires up to 0.035" diameter.

Indication for Use

The SCUBA™ Biliary Stent System is indicated for use in the palliation of malignant neoplasms in the biliary tree

Technological Characteristics

The SCUBA™ Biliary Stent System has the same design characteristics and intended use as the predicate devices. All of the stent systems are balloon-expandable stents mounted on an OTW delivery catheter. Diameters and lengths of the SCUBA Biliary Stent are within the size range of the predicate stents. The SCUBA Biliary Stent is manufactured from the same material used to manufacture the Medtronic RACER Biliary Stent.

Performance Data

Preclinical bench and biocompatibility testing was conducted to evaluate the safety and performance of the SCUBA Biliary Stent System. Testing included comparative testing with the predicate devices. Test results indicate that the SCUBA Biliary Stent System is safe and effective for the intended purpose, has comparable performance to the predicate devices, and is biocompatible.

Conclusion

The SCUBA Biliary Stent System is substantially equivalent to the Cordis PALMAZ® GENESIS™ Transhepatic Biliary Stent on OPTA™ PRO .035" Delivery System, and the Medtronic RACER Biliary Stent System, with respect to indication for use, stent material, and technological and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mr. Steve Camp
Vice President, Clinical and Regulatory Affairs
INVAtec, Inc.
3101 Emrick Blvd., Suite 113
BETHLEHEM PA 18020

MAR 1 5 2010

Re: K092352
Trade/Device Name: SCUBA Biliary Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: March 5, 2010
Received: March 8, 2010

Dear Mr. Camp:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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); 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 information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 796-5484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 796-5857 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zimmerman for

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092352

Device Name: SCUBA Biliary Stent System

Indications For Use: SCUBA Biliary Stent System is indicated for the palliation of malignant neoplasms in the biliary tree.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K092352