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(Posted November 13, 2003)

AUG 18 2008

510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name:	Abbott Vascular
Submitter's Address:	3200 Lakeside Drive Santa Clara, CA 95054
Telephone:	408-845-0613
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Contact Person:	Michelle Grossman, Senior Regulatory Affairs Associate
Date Prepared:	September 24, 2007
Device Trade Name:	Absolute® Pro .035 Biliary Self-Expanding Stent System
Device Common Name:	Biliary Stent
Device Classification Name:	Biliary Catheter
Device Classification:	Class II

Summary of Substantial Equivalence:

The Absolute® Pro .035 Biliary Self-Expanding Stent System is substantially equivalent to the Absolute®.035 Biliary Self-Expanding Stent System (K033393, cleared 11/10/03); and Xceed Nitinol Self Expanding Transhepatic Biliary Stent System (K050501, cleared 3/14/05).

Device Description:

The Absolute® Pro .035 Biliary Self-Expanding Stent System includes a self-expanding nickel titanium stent that is pre-mounted on an over-the-wire Delivery System. A total of 12 (6 at each end) radiopaque markers made of a radiopaque nickel titanium alloy are located at the ends of the stent. The Absolute Pro .035 Biliary Self-Expanding Stent System utilizes a 0.035" (0.89 mm) guide wire. The system includes radiopaque markers that identify the stent location.

The catheter comprises a retractable sheath that covers the stent during delivery, a radiopaque tip, an I-Beam to support the stent during deployment with an internal guide wire lumen, a detachable outer jacket, and a handle assembly with a safety lock and retraction features. With the handle in the unlocked position, rolling back the thumbwheel deploys the stent.

Intended Use:

The Absolute® Pro .035 Biliary Self-Expanding Stent System is intended for palliation of malignant strictures in the biliary tree.

Technological Characteristics Compared to Predicate:

A comparison of the technological characteristics of the Absolute® Pro .035 Biliary Self-Expanding Stent System and the predicate devices have been performed. The results of this comparison demonstrate that the Absolute® Pro .035 Biliary Self-Expanding Stent System is equivalent to the predicate devices.

Performance Data:

The results of the *in vitro* bench tests and analyses demonstrates that the Absolute® Pro .035 Biliary Self-Expanding Stent System is substantially equivalent in performance to the Absolute® .035 Biliary Self-Expanding Stent System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Michelle Grossman
Regulatory Affairs
Abbott Vascular – Vascular Solutions
3200 Lakeside Drive
SANTA CLARA CA 95054

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Re: K072708
Trade/Device Name: Absolute® Pro .035 Biliary Self-Expanding Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: July 15, 2008
Received: July 16, 2008

Dear Ms. Grossman:

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.

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.

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.

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.

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 (240) 276-0115. 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) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Christy Foreman for

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

Enclosure

Indications for Use

510(k) Number (if known): K072708

Device Name: Absolute® Pro .035 Biliary Self-Expanding Stent System

Indications for Use: The Absolute® Pro .035 Biliary Self-Expanding Stent System is intended for palliation of malignant strictures in the biliary tree.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 Reproductive, Abdominal, and Radiological Devices
510(k) Number K072708