AUG - 8 2003

Premarket Notification (510(k)) Summary

510(k) Number: K032206

Product Name: ParaMount™ Mini Stent and Delivery System (Biliary Indication)

Common Name: biliary stent

Class: Class II, 21 CFR 876.5010

Submitter's Name:
ev3 Inc.
4600 Nathan Lane North
Plymouth, MN 55442

Official Contact:
Glen D. Smythe
Regulatory Affairs Associate
Telephone: 651-697-4815
Fax: 651-697-2080

Summary Preparation Date: 15 July 2003

This summary is provided in compliance with section 513(I)(3)(A) of the Act and summarizes the safety and effectiveness information contained in this premarket notification submission for a modification to the IntraStent® DoubleStrut™ ParaMount™ Stent.

The ParaMount™ Mini Stent and Delivery Device is intended as a palliative treatment of malignant neoplasms in the biliary tree.

The ParaMount™ Mini Stent is a balloon expandable stainless steel stent with an open lattice design. The stent is electropolished. The device is provided premounted on a balloon delivery catheter. Upon balloon inflation the crimped stent expands to conform to the duct inner luminal surface and retains the expanded state upon balloon deflation.

The modified device is substantially equivalent* to the currently marketed stent and delivery system in intended use, materials, technological characteristics and performance. The stent was modified to provide increased radiopacity. Performance testing (bench) further supports a substantial equivalence claim. The collective evidence therefore provides assurance that the ParaMount™ Mini Stent and Delivery Device meet the requirements that are considered acceptable for the intended use.

*This document uses the term "substantial equivalence" as intended in 21 CFR 807.87, and not as defined in Title 36 of the US Code.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2003

Mr. Glen D. Smythe
Regulatory Affairs Associate
ev3, Inc.
4600 Nathan Lane North
PLYMOUTH MN 55442-2920

Re: K032206
Trade/Device Name: Paramount™ Mini Stent and Delivery System (Biliary Indication)
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: July 17, 2003
Received: July 18, 2003

Dear Mr. Smythe:

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 (301) 594-4616. 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,

Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032206

Device Name: ev3 ParaMount™ Mini Stent and Delivery System

FDA's Statement of the Indications For Use for device:

The ev3 ParaMount™ Mini Stent and Delivery System is intended as a palliative treatment for malignant neoplasms in the biliary tree.

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032206