510(k) Summary
Protégé® EverFlex™
Self-Expanding Biliary Stent System

MAR 18 2008

510(k) Number: K072301

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter/Contact Person:

Applicant (Manufacturer)	**ev3** 4600 Nathan Lane North Plymouth, MN 55442 Tel: (763) 398-7000 Fax: (763) 398-7200
Submitter's Name:	**ev3** 9600 Nathan Lane North Plymouth, MN 55442 Tel: (763) 398-7000 Fax: (763) 398-7200
Official Contact:	Bruce Backlund Sr. Regulatory Affairs Specialist **ev3** 4600 Nathan Lane North Plymouth, MN 55442 Tel: (763) 398-7612 Fax: (763) 398-7200 bbacklund@ev3.net

Summary Preparation Date: August 15, 2007

Device Name and Classification:

Trade Name:	Protégé® EverFlex™ Self-Expanding Biliary Stent System
Common Name/Usual Name:	Biliary Stent
Classification Name:	Biliary Catheter
Class:	Class II, 21 CFR 876.5010

Predicate Devices:

Protégé® EverFlex™ Self-Expanding Biliary Stent System (K060057)

Abbott Xpert™ Self-Expanding Transhepatic Biliary Stent System (K033537)

Bard® LUMINEXX™ Biliary Stent System (K003793)

Boston Scientific Sentinol ™ (K032025)

DYNALINK™ Biliary Self-Expanding Stent System (K002143)

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.

Device Description:
The PROTÉGÉ® EverFlex™ Self-Expanding Biliary Stent System is a self-expanding nitinol stent system intended for permanent implantation. The self-expanding stent is made of a nickel titanium alloy (nitinol) and comes pre-mounted on a 6F, 0.035" over-the-wire delivery system. The stent is cut from a nitinol tube in an open lattice design, and has tantalum radiopaque markers at the proximal and distal ends of the stent. Upon deployment, the stent achieves its predetermined diameter and exerts a constant, gentle outward force to establish patency.

Summary of Testing:
Biocompatibility: Biocompatibility was assessed and tested in accordance with ISO 10993 Part 1, "Biological Evaluation of Medical Devices," 1997(E) and FDA Memorandum #G95-1, "Biological Evaluation of Medical Devices".

Performance Data: Bench testing pertaining to performance characteristics was conducted on the 5mm Protégé EverFlex Self-Expanding Biliary Stent System and compared to the predicate device testing to demonstrate equivalency.

Statement of Equivalence:
The 5mm Protégé EverFlex Self-Expanding Biliary Stent System is substantially equivalent to the Protégé® EverFlex™ Self-Expanding Biliary Stent System (K060057), Bard® LUMINEXX™ Biliary Stent System (K003793), Abbott Xpert™ Self-Expanding Transhepatic Biliary Stent System (K033537) and Abbott DYNALINK™ Biliary Self-Expanding Stent System (K002143)

.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 18 2008

David Worrell, MS, RAC
Director, Regulatory Affairs
ev3® Inc.
9600 54th Avenue North
PLYMOUTH MN 55442-2111

Re: K072301
Trade/Device Name: Protégé® EverFlex™ Self-Expanding Biliary Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: December 14, 2007
Received: December 17, 2007

Dear Mr. Worrell:

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,

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

Enclosure

K072301

Indications for Use

510(k) Number (if known): K072301

Device Name: Protégé® EverFlex™ Self-Expanding Biliary Stent System

Indications for Use:

The Protégé® EverFlex™ Self-Expanding Biliary Stent System

is intended as a palliative treatment of malignant neoplasms 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)

Di[illegible]dominal,

an[illegible]

510(k) Number K072301