October 8, 2021

Invatec Innovative Technologies
Stephanie Isgrigg Robinson
Regulatory Affairs Specialist
4600 Nathan Lane North
Plymouth, Minnesota 55442

Re: K051917
Trade/Device Name: Diver C.E. Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Stephanie Isgrigg Robinson:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 8, 2005. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.10.08 10:38:24 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 8 - 2005

Invatec Innovative Technologies, S.R.
c/o Ms. Stephanie Isgrigg Robinson
Regulatory Affairs Specialist
4600 Nathan Lane North
Plymouth, MN 55442

Re: K051917
DIVER C.E. Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II (two)
Product Code: DXE
Dated: July 14, 2005
Received: July 15, 2005

Dear Ms. Robinson:

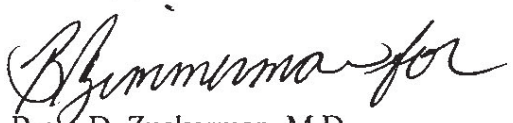
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K051917

Device Name: DIVER™ C.E. Catheter

Indications for Use:

The DIVER C.E. Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system.

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)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051917

AUG 8 - 2005

510(k) Summary
DIVER™ C.E. Catheter

510(k) Number: K051917

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

Submitter/Contact Person:

Applicant (Manufacturer):	Invatec Innovative Technologies Via Martiri della Libertà, 7 25030 Roncadelle (BS) Italy Tel: +39 030 258 93 11 Fax: +39 030 258 93 12
Submitter's Name:	**ev3** Inc. 4600 Nathan Lane North Plymouth, MN 55442 Tel: (763) 398-7000 Fax: (763) 398-7200
Official Contact:	Stephanie K. Isgrigg Robinson Regulatory Affairs Specialist **ev3** Inc. 4600 Nathan Lane North Plymouth, MN 55442 Tel: (763) 398-7487 Fax: (763) 398-7200 srobinson@ev3.net
Summary Preparation Date:	July 15, 2005

Device Name and Classification:

Trade Name:	DIVER™ C.E. Catheter
Common Name/Usual Name:	Catheter, Embolectomy
Classification Name:	Catheter, Embolectomy
Class:	Class II, 21 CFR 870.5150

Predicate Devices:

DIVER™ C.E. Catheter – K050276
Vascular Solutions Inc. PRONTO™ Extraction Catheter – K032763
VacLok™ Syringe – K994253
Hi-Flex™ High Pressure Tubing – K883718
Stopcock (One-port Manifold) – K934123

Device Description:

The DIVER C.E. Catheter is an aspiration catheter indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system. The catheter features an aspiration lumen running through the full length of the catheter. A luer lock type hub in the proximal end allows the connection of the catheter to the extension line (High Pressure Tubing), stopcock, and syringe that are included in the catheter package. The DIVER C.E. Catheter has a central aspiration lumen and a soft, atraumatic tip. The smooth, soft, atraumatic tip has a radiopaque marker band located at 1mm from its distal end. The DIVER C.E. Catheter is available in two configurations – with and without sideholes. The catheter is a rapid exchange design, with the guide wire lumen running from the distal tip to 22.7 cm proximally in the catheter body, where the exit port is located. The catheter is compatible with guide wires with a maximum diameter of 0.014". Additionally, a 40μ filter basket is also included to allow the physician to perform a post-procedure examination of the aspirated thrombi/emboli material removed during the procedure.

Intended Use:

The DIVER C.E. Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system.

Summary of Testing:

Sterilization: Results of sterilization validation demonstrate that the DIVER C.E. Catheter and its accessories are adequately sterilized.

Performance Data: The results of verification testing demonstrated that the DIVER C.E. Catheter and its accessories met the established acceptance criteria and performs in a manner equivalent to the predicate devices. No new safety or effectiveness issues were raised during the testing program.

Statement of Equivalence:

The DIVER C.E. Catheter and its accessories are substantially equivalent to the currently marketed DIVER C.E. Catheter (K050276), VacLok™ Syringe (K994253), Hi-Flex™ High Pressure Tubing (K883718) Stopcock (One-port Manifold) (K934123) and Vascular Solutions Pronto™ Extraction Catheter (K032763) in intended use, performance, technological characteristics and materials.