K024021

510(k) Summary

JAN 2 4 2003

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

Submitter	**ev3** 4600 NATHAN LANE NORTH PLYMOUTH, MN 55442
TRADE NAME	Nitrex™ Nitinol Guidewire
GENERIC CLASS	Guide wire
CLASSIFICATION	Class II (21 CFR 870.1330, 74 DQX)
SUBMITTED BY	ev3 Inc 4600 Nathan Lane Minneapolis, MN 55442
CONTACT	Phil Neururer Regulatory Affairs 763-398-7094
PREDICATE	Ultra-Select guidewire (K910280) FlexFinder guidewire (K893626, K943390)
DEVICE DESCRIPTION	The guidewire is constructed of nitinol (nickel-titanium alloy). The nitinol core extends from the distal tip of the guidewire to the proximal shaft end. The distal tip is a helically coiled coil gold plated tungsten wire. The guidewire is coated with a coating(s)to help facilitate smooth passage.
INDICATION FOR USE	The 0.035" and 0.025" Guidewire is indicated for use in the peripheral vasculature. The 0.014", 0.016", and 0.018" guidewires are indicated for use in the peripheral and coronary vasculature.
TESTING	Biocompatibility of the guidewire was verified in accordance with ISO 10993-1, Biological Evaluation of the Medical Devices. In-vitro performance testing of the guidewire included dimensional inspection, tensile strength tests, torque strength tests, coating performance test, and performance under simulated conditions. All testing of the product yielded acceptable results.
SUMMARY OF SUBSTANTIAL EQUIVALENCE	The Nitrex™ Nitinol Guidewire is substantially equivalent to the predicate device in intended use and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2003

EV3 Corporation
c/o Mr. Phil Neururer
Regulatory Affairs Associate
4600 Nathan Lane North
Plymouth, MN 55442

Re: K024021
Trade Name: Nitrex™ Nitinol Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: January 2, 2003
Received: January 3, 2003

Dear Mr. Neururer:

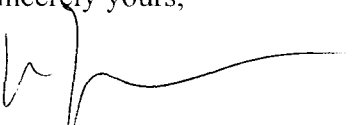
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 594-4646. 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

510 (k) Number (if known): K024021

Device Name: Nitrex™ Nitinol Guidewire

Indications For Use: The 0.035" and 0.025" Guidewire is indicated for use in the peripheral vasculature. The 0.014", 0.016", and 0.018" guidewires are indicated for use in the peripheral and coronary vasculature.

(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 Cardiovascular De

510(k) Number K024021

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