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Section 2 – 510(k) Summary

In accordance with 21 CFR §807.92, a 510(k) Summary for the IVT 0.014" PTFE-Coated Trackwire is presented on the following page.

DEC 11 1997

510(k) Summary

0008

Date: May 5, 1997

Submitter: InterVentional Technologies, Inc.
3574 Ruffin Road
San Diego, CA 92123
Tel: (619) 268-4488

DEC 11 1997

Contact Person: Kevin E. Daly
Director, Regulatory Affairs/Compliance Standards

Device Proprietary Name: IVT 0.014" PTFE-Coated Trackwire

Device Common Name: Catheter Guide Wire (§870.1330)

Predicate Devices: IVT 0.014" Trackwire;
ACS Hi-Torque Guide Wires with Microglide Coating;
Cordis Stabilizer Guidewires with Duraglide PTFE Coating.

Device Description: The IVT 0.014" PTFE-Coated Trackwires have a nominal diameter of 0.014 inches and nominal lengths from 175 to 300 centimeters. The distal 1-3 centimeters of the Trackwire is shapeable. The distal 2-6 centimeters contains a radiopaque coil. The proximal section of the Trackwire is coated with a fluorinated polymer.

Intended Use: The IVT 0.014" Trackwire is recommended for use to facilitate the navigation and placement of angioplasty interventional catheters through coronary and peripheral vessels. The 0.014" Trackwire is not indicated for cerebrovascular use.

Substantial Equivalence: The IVT 0.014" Trackwire is substantially equivalent to predicate 0.014" catheter guidewires. The technical characteristics of the 0.014" Trackwire do not introduce new questions regarding device safety and effectiveness. Biocompatibility and physical performance testing demonstrate that the IVT 0.014" Trackwire is suitable for its intended use.



Rockville MD 20857

DEC 11 1997

Mr. Kevin E. Daly
Director, Regulatory Affairs/Compliance Standards
InterVentional Technologies, Inc.
3574 Ruffin Road
San Diego, California 92123

Re: K971688
IVT 0.014" PTFE-Coated Trackwire
Regulatory Class: II (two)
Product Code: DQX
Dated: September 11, 1997
Received: September 15, 1997

Dear Mr. Daly:

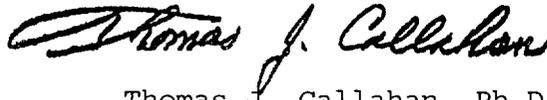
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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. 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Thomas J. Callahan". The signature is written in a cursive style with a large, prominent initial 'T'.

Thomas J. Callahan, Ph.D.
Director

Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971688

Device Name: IVT 0.014" PTFE-Coated Trackwire

Indications for Use: The IVT 0.014" PTFE-Coated Trackwire is indicated for use in coronary and peripheral vessels to facilitate the navigation and placement of angioplasty interventional catheters. The 0.014" Trackwire is not indicated for cerebrovascular use.

Tara A. Rea

(Division Sign-Off)
Division of Cardiovascular, ~~Respiratory~~
and Neurological Devices
510(k) Number K971688

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use