

### 510(k) SUMMARY

TherOx, Inc.  
2025 Newport Blvd., Suite 200  
Costa Mesa, CA 92627  
Phone: (714) 645-4271  
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NOV - 3 1997

#### Contact

Paul Zalesky, Ph.D.  
Chief Operating Officer

#### Classification

Wire, Guide  
Percutaneous Catheter

#### DESCRIPTION

TherOx Infusion Guidewires are intended for use in facilitating the placement of interventional devices in the cardiovascular and neurovascular system. TherOx Infusion Guidewires are designed for small vessel use.

TherOx Infusion Guidewires are also intended to be used for the controlled selective infusion of physician-specified fluid agents before, during or after interventional procedures in the cardiovascular or neurovascular system.

TherOx Infusion Guidewires are not intended for delivery of contrast agents. Fluid agents utilized with TherOx Infusion Guidewires should be fully prepared and used according to their manufacturer's instructions for use.

TherOx Infusion Guidewires are not intended for neonatal or pediatric use.

The TherOx Infusion Guidewire has an outside diameter of .014 in. and is available 180 cm and 300 cm in length, and is intended to pass freely thru standard catheters that have a thru lumen of .016 in. or larger.

The 300 cm TherOx Exchange Guidewire differs only in its overall length from the 180 cm TherOx Infusion Guidewire. The distal 180 cm of the TherOx Exchange Guidewire is identical to the 180 cm TherOx Infusion Guidewire. Only the proximal hypotube has been extended by 120 cm to achieve the 300 cm length. This extended proximal portion always remains outside the body and facilitates the replacement of one interventional device for another.

A proximal fluid connection is secured by connecting the proximal open end to a simple Tuohy-Borst connection. The infusion guidewire may be torqued by rotation of the torquing knob to direct the orientation of the distal tip.

## **TECHNOLOGICAL CHARACTERISTICS**

This product is equivalent in intended use as well as design, composition and function to the legally marketed Advanced Cardiovascular Systems 0.014" Hi Torque Floppy Guidewire and Hi Torque Exchange Guidewire and the legally marketed MediTech Katzen Infusion Wire (K883880).

## **SUMMARY OF STUDIES**

### **Performance Data**

#### **In Vitro Tests:**

Sample 2X sterilized (EtO) product was tested in vitro to assess all aspects of functionality and durability, evaluating each of the product's components. The product performance was also evaluated under simulated in vivo conditions via an aorta test fixture with indwelling PTCA catheter (*see schematics enclosed in Exhibit 2*). All bench testing was accomplished in accordance with the FDA's PTCA Catheter System Testing Guideline (Feb., 1989). Performance analysis assessed tensile testing, guidewire torque response, tip deflection and strength, joint integrity and strength, handling characteristics, fluid infusion characteristics, and product failure modes. Test results indicate that the Infusion Wire meets or exceeds its functional specification and is safe for its intended use.

Complete Infusion Wires were fabricated and inspected for dimensional conformance with the product specification. Length and O.D. measurements were made for the stainless steel coil, platinum coil, coil-to-coil screw joint, distal tip, core-to-hypotube joint, overall length, hypotube length and O.D., diffuser section, bond length and O.D., and polyimide-to-hypotube joint length and O.D. . All dimensions were within the design specifications.

### **RADIOPACITY**

Radiopacity tests were performed during animal studies under fluoroscopic guidance. The TherOx Infusion Guidewire demonstrated adequate radiopacity when compared with commercially available guidewires and vascular catheters.

### **BIOCOMPATIBILITY OF TEST MATERIALS**

Tests for biocompatibility of materials for the TherOx Infusion Guidewire were performed to establish that the materials used in the device met the qualifications for short-term use in the vascular system to comply with the standards set forth in the guidance documents in *Tripartite Agreement on Biocompatibility and ISO 10993-1*.

In determining biocompatibility test design, testing was selected as deemed appropriate for the type of tissue/device interface and the duration of patient exposure.

Biocompatibility testing was performed on sterile product.

TherOx feels that the biocompatibility test program used is appropriate and sufficient for a device that has less than 24 hours of tissue exposure.

TherOx feels the biocompatibility testing which was completed and passed, adequately addresses the issue of toxicological safety for this device's intended use.

### **In Vivo Tests**

In vivo animal studies were performed on 3 closed-chest dogs and 2 closed-chest pigs at 3 research centers to assess torque characteristics, maneuverability, tip-shaping, radiopacity, and compatibility with PTCA balloons and ancillary PTCA products.

The guidewire was directed to the heart by passing it through a guide catheter. Selected branches of the left and right coronary arteries were investigated. All studies were performed under fluoroscopic visualization.

A total of four commercially available guide catheters with multiple-tip configurations were utilized. Commercially distributed PTCA catheters manufactured by two companies, and of varying dimensions, were utilized to demonstrate compatibility with the TherOx Infusion Guidewire.

During the animal studies the TherOx Infusion Guidewire was tested against commercially available guidewires. The TherOx Infusion Guidewire performed comparable to commercially available guidewires when assessing maneuverability, compatibility, radiopacity and tip-shaping properties.

No complications were observed as a result of utilizing the TherOx Infusion Guidewire. The investigators concluded that the TherOx Infusion Guidewire could be advanced into the coronary arteries and small vessels. The TherOx Infusion Guidewire performed with relative ease and no arteriographic or physiologic evidence of vascular trauma was observed.

### **CLINICAL STUDY**

Clinical studies demonstrated the TherOx Infusion Guidewire performed comparably as an accessory device, for commercially available interventional devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Paul J. Zalesky, Ph.D.  
TherOx, Inc.  
2025 Newport Boulevard  
Costa Mesa, California 92627

Re: K971719  
TherOx Infusion Guidewires  
Regulatory Class: II (two)  
Product Code: 74 DQX  
Dated: August 30, 1997  
Received: September 4, 1997

Dear Dr. Zalesky:

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 (Pre-market 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 requirement, 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.

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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) 594-4639. 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,



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: K971719

Device Name: TherOx Infusion Guidewires

Indications for Use:

TherOx Infusion Guidewires are intended for use in facilitating the placement of interventional devices in the cardiovascular and neurovascular system. TherOx Infusion Guidewires are designed for small vessel use.

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*T. A. Rupp*

(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K971719

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

Concurrence of DCRH, Office of Device Evaluation (ODE)

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over the Counter Use \_\_\_\_\_