

II. 510(k) SUMMARY

Date: March 12, 1998

Applicant's Address: Piolax, Inc.
51, Iwai-Cho, Hodogaya-Ku
Yokohama 240-0023
Japan

Manufacturing Facility Address:

179, Kariba-Cho, Hodogaya-Ku
Yokohama 240-0025
Japan

Contact Person: M. Elizabeth Bierman, Esq.
Morgan, Lewis & Bockius LLP
1800 M Street, N.W.
Washington, D.C. 20036
Tel: 202/467-7206
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Trade Name: Piolax Hydrophilic Guidewire

Classification Name: Catheter Guidewire

Usual/Common Name: Catheter Guidewire

Legally Marketed
Predicate Device:

Terumo Radifocus® Guidewire M (K924202)

Device Description:

The Piolax Hydrophilic Guidewire is a tapered wire, composed of stainless steel or Ni-Ti alloy that is coated with a hydrophilic polymer. The hydrophilic polymer is composed of polyvinyl pyrrolidone and benzoyl peroxide. The Guidewire is provided with one of three differently shaped hydrophilic polymer-coated tips (i.e., straight, angled, J-shaped). The standard wire diameters are 0.58 mm, 0.72 mm, 0.79 mm, and 0.86 mm. The range for length of guidewires is 450 to 3,000 mm.

Intended Use:

The Piolax Hydrophilic Guidewire is a catheter guidewire, coated with a hydrophilic polymer in order to reduce frictional resistance in two phases between the wire and the blood vessel and between the wire and the inner surface of the catheter, thereby allowing the Guidewire to more easily reach the intended area. The Piolax Hydrophilic Guidewire is intended for vascular therapeutic and diagnostic applications, particularly for arterial and venous applications in the cardiac, cerebral, and abdominal regions.

The Piolax Hydrophilic Guidewire is contraindicated for use in coronary vessels.

Technological Characteristics:

The Piolax Hydrophilic Guidewire is composed of materials similar to that of the Terumo Radifocus® Guidewire. Both are composed of a stainless steel or similar alloy, with a urethane resin layer, and both have a hydrophilic polymer coating material. The Piolax Hydrophilic Guidewire differs in that its primary layer includes another resin (in addition to the urethane resin), that serves as a primer for the hydrophilic coating. Additionally, the composition of the hydrophilic coating differs. The diameters and lengths of the two wires are similar.

Performance Data:

Piolax conducted tensile strength, torque strength, torqueability, tip flexibility, and coating adherence testing consistent with FDA's Coronary and Cerebrovasculature Guidewire Guidance (Jan. 1995). The test results demonstrate that the Piolax Hydrophilic Guidewire is substantially equivalent to the Terumo Radiofocus® Guidewire.

In addition, Piolax conducted the following biocompatibility tests: pyrogen rabbit extract test; hemolytic extract test; cytotoxicity test; sensitization test; intracutaneous reaction test; acute systemic toxicity test; blood compatibility test; and USP rabbit pyrogen test. All tests demonstrated that the Piolax Hydrophilic Guidewire is biocompatible.

Shelf-life testing on the Piolax Hydrophilic Guidewire demonstrates that the device has a shelf-life expiration date of two years.

Based on results of the above testing, Piolax concludes that the Piolax Hydrophilic Guidewire is as safe and as effective as Terumo's Radifocus® Guidewire.



OCT 27 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Piolax, Inc.
c/o Ms. M. Elizabeth Bierman, Esq.
Morgan, Lewis and Bockius LLP
1800 M Street, N.W.
Washington, D.C. 20036

Re: K980977
Trade Name: Piolax Hydrophilic Guidewire
Regulatory Class: II
Product Code: DQX
Dated: October 14, 1998
Received: October 14, 1998

Dear Ms Bierman:

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 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. 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) 594-4586. 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" (21CFR 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/dsma/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 (if known): K980977

Device Name: Piolax Hydrophilic Guidewire

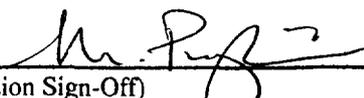
Indications for Use:

The Piolax Hydrophilic Guidewire is indicated for use for introduction and positioning of catheters within the peripheral vasculature in vascular diagnostic and therapeutic applications, particularly for arterial and venous applications in the cardiac, cerebral, and abdominal regions. The Guidewire is contraindicated for use in coronary vessels.

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

CONCURRENCE OF CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use
(Per 21 CFR § 801.109)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K980977

(Optional Format 1-2-96)