K041740

SECTION 4.0 510(k) SUMMARY INFORMATION

Submitter:	ARROW International, Inc. 2400 Bernville Road Reading, PA 19605-9607 USA
Contact person:	Suzanne Schorle Regulatory Affairs Associate Phone: 610-378-0131, ext. 3443 Fax: 610-478-3167 Email: suzanne.schorle@arrowintl.com
Date summary prepared:	June 24, 2004
Device trade name:	Silicone Coated Guidewire
Device common name:	Silicone Coated Guidewire
Device classification name:	Guidewire
Legally marketed devices to which the device is substantially equivalent:	K905581 Lake Region Mfg. Silicone Coated Guidewire
Description of the device:	The proposed device is a silicone coated stainless steel guidewire. It consists of a coiled wire around a solid stainless steel core wire. The internal core wire is secured at both ends to the outer core wire. These guidewires are used to place intravascular catheters.
Intended use of the device:	The Arrow guide wire will be used to facilitate the placement of catheters during diagnostic and interventional procedures.
Technological characteristics:	The proposed guidewires have the same technological design characteristics as the predicate devices.
Performance tests:	The following tests were performed to demonstrate substantial equivalence: • Tensile Strength • Catheter Compatibility • Coating Durablity/Lubricity • Flexing Test • Fracture Test • Tip Flexibility
Conclusions:	The results of the laboratory tests demonstrate that the guidewires are substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2004

Arrow International
c/o Ms. Suzanne Schorle
Regulatory Affairs Associate
2400 Bernville Road
Reading, PA 19605

Re: K041740
Trade/Device Name: Silicone Coated Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: September 2, 2004
Received: September 3, 2004

Dear Ms. Schorle:

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 (240) 276-0120. 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,

Donna R. Lechner

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

Enclosure

SECTION 3.0 INDICATIONS FOR USE STATEMENT

510(k) Number: K041740

Device Name: Silicone Coated Guidewire

Indications for Use: To facilitate the placement of devices used during diagnostic and interventional procedures.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 Devices

510(k) Number K041740