K071111 1/2

JUL 17 2007

510 (k) Summary

Submitter:	ARROW International, Inc. 2400 Bernville Road Reading, PA 19605-9607 USA
Contact person:	Karl Nittinger Regulatory Affairs Specialist Phone: 610-378-0131, ext. 3405 Fax: 610-478-3128 Email: karl.nittinger@arrowintl.com
Date summary prepared:	April 11, 2007
Device trade name:	Non-Absorbable Silk Suture (21 CFR 878.5030, Product Code GAP)
Device common name:	Suture
Device classification name:	Natural non-absorbable silk surgical suture.
Legally marketed devices to which the device is substantially equivalent:	Surgical Specialties, Inc. Non-Absorbable Silk Suture (K930826) and Ethicon, Inc., Perma-Hand™ Non-Absorbable Silk Suture (N11397)
Description of the device:	The Arrow Non-Absorbable Silk Suture has the following characteristics: • Black, braided silk suture thread of '000' (Metric 2) diameter • 30" (75 cm) suture thread length • Pre-attached, straight, stainless steel needle • 2-3/8" (60 mm) needle length
Indications for use:	The non-absorbable silk suture is intended for use in general soft tissue approximation, excluding use in cardiovascular, ophthalmic and neurological tissues.
Technological characteristics:	The proposed non-absorbable silk suture has the same technological design characteristics as the predicate devices.

K071111 2/2

Performance tests:	The following tests were performed to demonstrate substantial equivalence: • Suture Tensile Strength (USP 29<881>:2006) • Needle Attachment (USP 29<871>:2006) • Suture Diameter (USP 29<861>:2006 • Biocompatibility (ISO 10993-1:2003)
Assessment of non-clinical performance data:	The results of the bench tests demonstrate that Arrow's non-absorbable silk suture is safe, effective and performs favorably when compared to the Surgical Specialties, Inc. and Ethicon, Inc. predicate sutures.
Summary	Arrow International's Non-Absorbable Silk Suture has the same intended use as the Ethicon, Inc. predicate device. Based on the assessment of non-clinical performance data to verify this new intended use, and the technological characteristic comparison, Arrow's non-absorbable silk suture is 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

JUL 17 2007

Arrow International Inc.
% Mr. Karl J. Nittinger
Regulatory Affairs Specialist
P.O. Box 12888
Reading, Pennsylvania 19612

Re: K071111
Trade/Device Name: Non-Absorbable Silk Suture
Regulation Number: 21 CFR 878.5030
Regulation Name: Natural nonabsorbable silk surgical suture
Regulatory Class: II
Product Code: GAP
Dated: April 11, 2007
Received: April 20, 2007

Dear Mr. Nittinger:

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) 276-0115. 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 (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071111 1/1

Indications for Use Statement

510(k) Number (if known):

Device Name: Non-Absorbable Silk Suture

Indications for Use: The non-absorbable silk suture is intended for use in general soft tissue approximation, excluding use in cardiovascular, ophthalmic and neurological tissues.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 General, Restorative, and Neurological Devices

510(k) Number K071111