SEP 1 9 2001

K012124

Johnson & Johnson Medical (China) Ltd.
强生(中国)医疗器材有限公司

#660 Xin Hua Road, Man Po International Center, 3rd Floor, Shanghai 200052, China
Tel: 8621-62826988 Fax: 8621-62825037

510(K) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92.

"The assigned 510(K) number is : _____"

Applicant: Johnson & Johnson Medical (China) Ltd.
#660 Xin Hua Road, Man Po International Center, 3rd Floor
Shanghai 200052, China
Tel: 8621-62826988 Fax: 8621-62825037

Contact: Ben Tang
#75 Nan Gu Zhi Road, Minhang, Shanghai 200245, China
Tel: 6821-64635010 Fax:8621-64622528

Date: March 30, 2001

Name of Device:
Common or Usual Name: Silk Nonabsorbable Surgical Sutures.
Classification Name: Suture, Nonabsorbable, Silk.
Proprietary/Trade Name: Mersilk® Black Silk Braided Non-absorbable suture, USP.

Predicate Device Information:
ARC Medical Supplies (beijing) Co., Ltd..
Silk Nonabsorbable Surgical Suture, USP.
510(K) number is K000541.

Device Description:
The black silk braided nonabsorbable sutures, USP, manufactured by Johnson & Johnson Medical (China) Ltd. can be braided, coated with wax, dyed black (Logwood), available in a range of gauge sizes and lengths, and attached to stainless steel needles of varying types and sizes. (See sec 5.0 Device Description)

Intended Use:
The black silk braided nonabsorbable sutures, USP, are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures. (See sec 3.0 Labeling)

Technological Characteristics:
All the equipment and processes concerned with product quality have been validated before put into place. Process of gamma sterilization, implemented by contract sterilizer, is validated and approved in conformance to corporate and international regulations. The gamma sterilization is conducted and monitored according to established procedures. (See sec 8.0 Sterilization)

The established procedures define the criteria of acceptance and rejection for incoming material, in process material and finished goods. The requirements are stricter than or in conformance to that of USP. (See sec 9.0 Manufacturing and Quality Assurance)

Testing of suture diameter, suture length, knot pull tensile strength and needle attachment strength according to methods outlined in USP XXIIII demonstrates that Johnson & Johnson Medical (China) Ltd. silk surgical sutures meet or exceed USP specifications. The additive (Logwood) content is in conformance with the requirement addressed in *Handbook of U.S. Colorants: Foods, Drugs, Cosmetics and Medical Device, version 3.* (See sec 6.0 Performance)

Labeling comply with the specific requirement of USP XXIIII, and the symbol on the packaging comply with the requirements of ISO/TR 15223 Medical Devices—Symbols to be Used with Medical Device Labels, Labeling and Information to be Supplied (See section 3.0 Labeling).

Performance Data:
Mersilk® Black Silk Braided Non-absorbable suture, USP, meet or exceed the requirements of USP XXIIII. And the additives including Loogwood and coating wax, are proved to be nontoxic. (See section 6.0 Performance and section 7.0 Biocompatibility)

Substantial Equivalence:
The black silk braided nonabsorbable sutures, USP, have the same intended use, and similar principles of operation and technological characteristics as the predicate device. Moreover, various testing and clinical study contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, Mersilk® Black Silk Braided Non-absorbable sutures, USP, are substantially equivalent to the predicate devices. (See sec 10.0 Comparison)

Comparison to Predicate Devices:
The black silk braided nonabsorbable sutures, USP, are substantially equivalent to the silk nonabsorbable surgical sutures, USP, manufactured by ARC Medical Supplies (Beijing) Co., Ltd..

Simon Li, Managing Director

April 25, 2001
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2001

Johnson & Johnson Medical (China) Ltd.
c/o Mr. Ben Tang
Quality Assurance Manager
#75 Nan Gu Zhi Road, Minhang
Shanghai 200245
China

Re: K012124
Trade/Device Name: Mersilk Black Silk Braided Non-absorbable Suture
Regulation Number: 878.5030
Regulation Name: Non-absorbable silk suture
Regulatory Class: II
Product Code: GAP
Dated: March 30, 2001
Received: July 6, 2001

Dear Mr. Tang:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Susan Walker, MD

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012124

Device Name: Mersilk Black Silk Braided Non-absorbable Suture

Indications For Use:

Silk suture is indicated for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic and neurological procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

K012124

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012124