510(k) Number: K091574

510(k) SUMMARY
(As Required by 21 CFR 807. 92)

Submitted by:

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OCT - 9 2009

Date of Summary: May 1st, 2009

Device Name: AMERICAN SUTURE™ Non Absorbable Surgical Sutures with/without Needles (Silk, Nylon, Polypropylene, and Polyester)

Common Name: Surgical Sutures

Classification Name: Sutures

Class: 2

Product Code: GAT, GAW, GAP, and GAR

Regulation Number: 21 CFR 878-5000, 5010, 5020, and 5030

Predicative Device: CP Medical Non-absorbable Surgical Sutures

510 K Number	Product Description
K001184	Silk Non-absorbable Surgical Sutures
K001173	Nylon Non-absorbable Surgical Sutures
K001185	Polypropylene Non-absorbable Surgical Sutures
K001172	Polyester Non-absorbalbe surgical Sutures

Modifications: There are no modifications to the device design that affect safety and effectiveness for its intended use.

Device Description AMERICAN SUTURE™ Non-Absorbable Surgical Sutures with/without Needle are Single Use, Sterile, Non-Pyrogenic devices used for safe and reliable soft tissue approximation, wound closure, and ligation.

Intended Use: **For safe and reliable soft tissue approximation, wound closure and ligation.**

Technological AMERICAN SUTURE™ Non-Absorbable Surgical Sutures with/without Needle have the same technological characteristics as the legally marketed CP Medical Non-absorbable Surgical Sutures.

Technical Comparison to Predicative Devices

American™ Non Absorbable Surgical Sutures	CP Medical Non Absorbable Surgical Sutures
American Surgical Sutures are indicated for soft tissue approximation and ligation	CP Medical non Absorbable Sutures are indicated soft tissue approximation and ligation.
American Silk sutures are Intended for Use in gastrointestinal, neurological, and cardiovascular surgery	CP Medical sutures are Intended for Use in gastrointestinal, neurological, and cardiovascular surgery
American Sutures are made of Silk, Nylon, Polypropylene, and Polyester materials. Sterile, Single Use, Non Absorbable. With or without Needles attached	CP Medical Sutures made of Silk, Nylon, Polypropylene and Polyester materials. Sterile, Single Use, Non Absorbable. With or without Needles attached.
American Silk sutures are made from pure Silk monofilaments, braided then coated with Silicone	CP Medical Silk Sutures are braided from pure Silk Monofilaments, braided then coated with Silicone
American Nylon Sutures are made from monofilaments of a polyamide material and dyed colored Black or Blue	CP Medical sutures are made from monofilaments polyamide material and dyed colored Black or Blue
American Polypropylene sutures are made from Monofilaments of synthetic Polyolefin	CP Medical Polypropylene sutures are made from monofilaments of synthetic Polypropyelene [1]
American Polyester Sutures are made from monofilaments of synthetic Polyethylene , braided then coated with Silicone	CP Medical Polyester sutures are made form monofilaments of synthetic Polyethylene, braided, then coated with Silicone
American Surgical Sutures meet or exceed the performance requirements for Non-Absorbable surgical sutures as defined in the Official monograph of the United States Pharmacopeia: Diameter <861> Tensile Strength <881> Needle Attachment ,871> Suture Length Requirement	CP Medical Sutures meet or exceed the performance requirements for Non-Absorbable surgical sutures as defined in the Official monograph of the United States Pharmacopeia: Diameter <861> Tensile Strength <881> Needle Attachment <871> Suture Length Requirement
American surgical Sutures are offered with or without Needles	CP Medical sutures are offered with or without Needles

[1] Polyolefin and Polypropylene are both synthetic polymers widely used in the manufacturing of surgical sutures.

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Testing:

AMERICAN SUTURE™ Non-Absorbable Surgical Sutures with/without Needle have been subjected to performance and safety testing to verify mechanical properties and functioning, as well as biocompatibility and sterility.

The American Sutures™ Surgical sutures intended to be introduced have been tested for performance and safety in conformance with the following test methods:

FDA Recognized Standards

- AAMI / ANSI / ISO 10993-5:1999, Biological evaluation of medical devices -- Part 5: Tests for In Vitro Cytotoxicity. (Biocompatibility)
- AAMI / ANSI / ISO 10993-10:2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity. (Biocompatibility)
- AAMI / ANSI / ISO 11135-1:1995 Validation and routine control of ETO Sterilization
- AAMI / ANSI / ISO 11137-1:2000 Validation and routine control of GAMMA Sterilization

Currently FDA recognized USP Edition Monographs

USP 30 <861>:2007 Sutures Diameter
USP 30 <871> 2007 Sutures Needle Attachment
USP 30 <881>:2007 Sutures Tensile Strength

Mexican Norms.

Federal Mexican Code for Medical Devices - F.E.U.M. 2006 (Mex. Pharmacopoeia)
FEUM- MGA-DM-3171, pages 220-221- Intracutaneous Irritation Test
FEUM-MGA-DM-3083, pages 217-220 – Systemic Injection Test
FEUM-MGA-DM-3081, pages 215-216 Implantation Test

Official Mexican Norms NOM-067-SSA-1993 for Medical Sutures
NOM –B-1-70 Analysis Methods for Steels and Smelting (Needles)
NOM –B-119-78 Determination of Rockwell Hardness for Metals (Needles)
NOM-BB-46-76 Determination of Corrosion Resistance for Hypodermic Needles

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Suplidores unidos Internacionales S.A.
% VHP Consulting
Mr. Victor Pereira
P.O. Box 97-0132
Coconut Creek, Florida 33067-0132

OCT - 9 2009

Re: K091574
Trade/Device Name: AMERICAN SUTURE™ Surgical Sutures – SILK BLACK – Braided
AMERICAN SUTURE™ Surgical Sutures – NYLON BLACK and BLUE – Braided
AMERICAN SUTURE™ Surgical Sutures – POLYPROPYLENE
AMERICAN SUTURE™ Surgical Sutures – POLESTER - Braided
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: August 1, 2009
Received: August 11, 2009

Dear Mr. Pereira:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K091574

Device Name: AMERICAN SUTURE™ Surgical Sutures- SILK BLACK - Braided

INDICATIONS FOR USE:

General soft tissue approximation and/or ligation including use in Cardiovascular, Opthalmic, and Neurological procedures.

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)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091574

INDICATIONS FOR USE STATEMENT

510(k) Number: K091574

Device Name: AMERICAN SUTURE™ Surgical Sutures- NYLON BLACK and BLUE - Braided

INDICATIONS FOR USE:

General soft tissue approximation and/or ligation including use in Cardiovascular, Opthalmic, and Neurological procedures.

Prescription Use__X__ AND/OR Over- The Counter Use:____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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INDICATIONS FOR USE STATEMENT

510(k) Number: K091574

Device Name: **AMERICAN SUTURE™ Surgical Sutures- POLYPROPYLENE**

INDICATIONS FOR USE:

General soft tissue approximation and/or ligation including use in Cardiovascular, Opthalmic, and Neurological procedures.

Prescription Use__X__ AND/OR Over- The Counter Use:____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Division of Surgical, Orthopedic,
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INDICATIONS FOR USE STATEMENT

510(k) Number: K091574

Device Name: **AMERICAN SUTURE™ Surgical Sutures- POLESTER - Braided**

INDICATIONS FOR USE:

General soft tissue approximation and/or ligation including use in Cardiovascular, Opthalmic, and Neurological procedures.

Prescription Use__X__ AND/OR Over- The Counter Use:____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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