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510(k) Summary

As required by section 807.92(c)

JUN - 9 2008

The Assigned 510(k) Number is: K080684

Submitter Information:

Manufacturer Name:
Foosin Medical Supplies Inc., Ltd.
No.312, Shichang Road
Weihai, Shandong, China, 264209

Contact Person of the Submission:
Ms. Diana Hong
Mr. Eric Chen
Shanghai Mid-Link Business Consulting Co., Ltd
Suite 8D, Zhongxin Zhongshan Mansion,
No.19, Lane 999, Zhong Shan Nan Er Road
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eric.chen@mid-link.net

Subject Device Information

1. Nonabsorbable Silk Suture with Needle

1.1 Applicant Device Information

Trade/Proprietary Name: WG-Surgical Sutures with Needle
Common Name: Nonabsorbable Silk Suture with Needle
Classification Name: Suture, Nonabsorbable, Silk
Device Class: II
Product Code: GAP
Regulation Number: 878.5030
Review Panel: General & Plastic Surgery
Intended Use:
Nonabsorbable Silk Suture with Needle is indicated for use in general soft tissue approximation

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and/or ligation including use in cardiovascular, ophthalmic and neurological procedures.

1.2Predicate Device

K-number: K041514

1.3 Device Description

The applicant devices of nonabsorbable silk suture with needle consist of a silk surgical suture made of natural silk and a stainless steel needle. It is EO sterilized, and prygon-free. Nonabsorbable silk suture is braided.

1.4 Substantially Equivalence Determination

The applicant device of nonabsorbable silk surgical suture is substantially equivalent to the predicate device.

2. Nonabsorbable Polypropylene Suture with Needle

2.1Applicant Device Information

Trade/Proprietary Name: WG-Surgical Sutures with Needle

Common Name: Nonabsorbable Polypropylene Suture with Needle

Classification Name: Suture, Nonabsorbable, Synthetic, Polypropylene

Device Class: II

Product Code: GAW

Regulation Number: 878.5010

Review Panel: General & Plastic Surgery

Intended Use:

Nonabsorbable Polypropylene Suture with Needle is indicated for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic and neurological procedures.

2.2Predicate Device

K-number: K070243

2.3Device Description

The applicant devices of nonabsorbable polypropylene suture with needle consist of a silk surgical suture made of polypropylene and a stainless steel needle. It is unbraided. It is EO sterilized, and prygon-free.

2.4Substantially Equivalence Determination

The applicant device of Nonabsorbable polypropylene Suture with Needle is substantially equivalent to the predicate device.

3. Nonabsorbable Polyester Suture with Needle

3.1Applicant Device Information

Trade/Proprietary Name: WG-Surgical Sutures with Needle

Common Name: Nonabsorbable Polyester Suture with Needle

Classification Name: Suture, Nonabsorbable, Synthetic, Polyethylene

Device Class: II

Product Code: GAT

Regulation Number: 878.5000

Review Panel: General & Plastic Surgery

Intended Use:

Nonabsorbable Polyester Suture with Needle is indicated for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic and neurological procedures.

3.2Predicate Device

K-number: K060165

3.3Device Description

The applicant devices of nonabsorbable polyester suture with needle consist of a polyester surgical suture made of polyester and a stainless steel needle. It is unbraided. It is EO sterilized, and prygon-free.

3.4Substantially Equivalence Determination

The applicant device of Nonabsorbable Polyester Suture with Needle is substantially equivalent to the predicate device.

4.Nonabsorbable Polyamide Suture with Needle

4.1Applicant Device Information

Trade/Proprietary Name: WG-Surgical Sutures with Needle

Common Name: Nonabsorbable Polyamide Suture with Needle

Classification Name: Suture, Nonabsorbable, Synthetic, Polyamide

Device Class: II

Product Code: GAR

Regulation Number: 878.5020

Review Panel: General & Plastic Surgery

Intended Use:

Nonabsorbable Polyamide suture with needle is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures.

4.2Predicate Device

K-number: K0060471

4.3Device Description

The applicant devices of nonabsorbable polyamide suture with needle consist of a polyamide surgical suture made of long-chain, aliphatic polymers nylon and a stainless steel needle. It is unbraided. It is EO sterilized, and prygon-free.

4.4Substantially Equivalence Determination

The applicant device of nonabsorbable polyamide suture with needle is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2008

Foosin Medical Supplies Inc.
% Shanghai Midlink Business
Consulting Co., Ltd.
Ms. Diana Hong
Suite 8D, Zhongxin Zhongshan Mansion
No. 19, Lane 999, Zhongshan No. 2 Road (S)
Shanghai 20030
China

Re: K080684
Trade/Device Name: Nonabsorbable Silk Suture with Needle, Nonabsorbable Polypropylene Suture with Needle, Nonabsorbable Polyester Suture with Needle, Nonabsorbable Polyamide suture with needle
Regulation Number: 21 CFR 878.5030
Regulation Name: Natural nonabsorbable silk surgical suture
Regulatory Class: II
Product Code: GAP, GAW, GAT, GAR
Dated: May 2, 2008
Received: May 5, 2008

Dear Ms. Hansen:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K080684

Device Name: Nonabsorbable Silk Suture with Needle

Indications for Use:

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

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden for

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

510(k) Number K080684

Indications for Use

510(k) Number: K080684

Device Name: Nonabsorbable Polypropylene Suture with Needle

Indications for Use:

Nonabsorbable Polypropylene Suture with Needle is indicated for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic and neurological procedures.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxn

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

510(k) Number K080684

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Indications for Use

510(k) Number: K080684

Device Name: Nonabsorbable Polyester Suture with Needle

Indications for Use:

Nonabsorbable Polyester Suture with Needle is indicated for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic and neurological procedures.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M.A. Hyde

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

510(k) Number K080684

Indications for Use

510(k) Number: K080684

Device Name: Nonabsorbable Polyamide suture with needle

Indications for Use:

Nonabsorbable Polyamide suture with needle is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K080684