DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 29 2010

MYCO Medical Supplies, Inc.
% Mr. Raji Juma
101 Rose Valley Woods Drive
Cary, North Carolina 27513

Re: K982646
Trade/Device Name: Ailee Sutures and Ailee Needles
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: Class II
Product Code: GAW, GAL, GAP, GAS, GAR, GAM, GAN, and GAO
Dated: April 6, 1999
Received: April 6, 1999

Dear Mr. Juma:

This letter corrects our substantially equivalent letter of June 2, 1999.

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 (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.

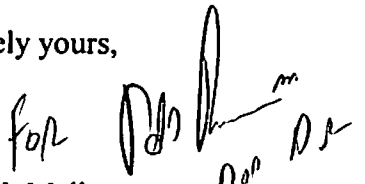
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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
Center for Devices and
Radiological Health

K982646

510 (k) Number (if known): K982646

Device Name: Chromic Gut

Indication For Use:

Chromic Gut surgical sutures are indicated for use as absorbable sutures in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but NOT for use in cardiovascular and neural tissue.

(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 Devices
510(k) Number K982646

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

K982646

Page 1 of 1

510 (k) Number (if known): K982646

Device Name: Catgut plain

Indication For Use:

Catgut plain surgical sutures are indicated for use as absorbable sutures in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but NOT for use in cardiovascular and neural tissue.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982646

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

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510 (k) Number (if known): K982646

Device Name: Polyglycolic acid sutures

K982646/S3

Indication For Use:

Polyglycolic acid sutures are indicated for use as absorbable sutures in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but NOT for use in cardiovascular and neurological tissues.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982646

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

S/S 32

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K982646

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FDA/CDRH/ODE/DMC

510 (k) Number (if known): K982646

Device Name: Silk sutures

Indication For Use:

Silk sutures are indicated for use as non-absorbable sutures in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, neural tissue.

(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 Devices
510(k) Number K982646

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

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K982646

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FDA/CDRH/ODE/DMC

510 (k) Number (if known): K982646

Device Name: Polyester sutures

Indication For Use:

Polyester sutures are indicated for use as non-absorbable sutures in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, neural tissue.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982646

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)

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K982646

510 (k) Number (if known): K982646

Device Name: Nylon sutures

Indication For Use:

Nylon sutures are indicated for use as non-absorbable sutures in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, neural tissue.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982646

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

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K982646

510 (k) Number (if known): K982646

Device Name: Polyproylene sutures

Indication For Use:

Polyproylene sutures are indicated for use as non-absorbable sutures in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, neural tissue.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982646

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)

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