JINHUAN
Medical Products

Shanghai Pudong Jinhuan Medical Products Co., Ltd
25 Lianzhen Road, Pudong New Area,
Shanghai 201204, P.R.CHINA.
TEL: 021-50910082 FAX: 021-58915884

9. 510(K) SUMARY

510(K) SUMMARY

[as required by 807.92(c)]

Submitter of 510(k): Shanghai Pudong Jinhuan Medical Products Co., Ltd.
25 Lianzhen Road, Pudong New Area,
Shanghai 201204, P.R.CHINA.
TEL: 021-50910082 FAX: 021-58915884
E-mail: Jinhuan@sh-Jinhuan.com

Contact Person: Chen Xiuqin

Date of Summary: Oct 15, 2007

Trade/Proprietary Name: Shanghai Pudong Jinhuan Medical Products Co., Ltd.

Product Code: GAM

Predicate Device: K984374 Samyang Corporation
K951352 DAVIS & GECK, INC.

Intended Use:

Absorbable Synthetic Suture with Needle Attachment (PGA BRAIDED) is indicated for use in general soft tissue approximation including ophthalmic surgery. Absorbable Synthetic Suture with Needle Attachment (PGA BRAIDED) is not indicated for cardiovascular and neurological tissue approximation.

Device Description:

Absorbable Synthetic Suture with Needle Attachment (PGA BRAIDED) is a synthetic absorbable suture based on Polyglycolic acid.

Absorbable Synthetic Suture with Needle Attachment (PGA BRAIDED) coated with polycaprolactone and calcium stearate, has been found to be inert, non-antigenic and nonpyrogenic. Absorbable Synthetic Suture with Needle Attachment (PGA BRAIDED) are

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available dyed (violet) and undyed. Absorbable Synthetic Suture with Needle Attachment (PGA BRAIDED) complies with the requirements of USP and EP.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Shanghai Pudong Jinhuan Medical
Products Co., Ltd.
% PATS Corporation
Mr. Brandon Choi
General Manager
49 Candlewood Way
Buena Park, California 90621

SEP - 4 2008

Re: K080412
Trade/Device Name: Absorbable Synthetic Suture with Needle Attachment (PGA BRAIDED)
Regulation Number: 21 CFR 878.4493
Device Name: Absorbable poly(glycolide/L- lactide) surgical suture
Regulatory Class: II
Product Code: GAM
Dated: August 21, 2008
Received: August 26, 2008

Dear Mr. Choi:

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

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 (if known):

Device Name: Absorbable Synthetic Suture with Needle Attachment (PGA BRAIDED)

Indications for Use: Absorbable Synthetic Suture with Needle Attachment (PGA BRAIDED) is indicated for use in general soft tissue approximation including ophthalmic surgery. Absorbable Synthetic Suture with Needle Attachment (PGA BRAIDED) is not indicated for cardiovascular and neurological tissue approximation.

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 K080912