JUN 1 1 1998

510(k) Summary
[As required by Section 807.92(a)]

K980899

1) The Name of Submitter:

Kenshin Trading Corporation
1815 West 213th Street Suite 180
Torrance, CA 90501
Phone: (310)212-3199
Fax: (310)212-3299
Contact person: Kunio Suzuki
Date of preparation: May 15, 1998

2) The Name of Device:
JIN Acupuncture Needle
Single Use Sterile Acupuncture Needles
Class: II
Product Code: MQX
Panel Code: General Hospital

3) Identification of the legally marketed device to which the submitter claims equivalence:

	510(k) Number	Trade Name	Manufacturer
1)	K963194	ITO	Ito Co. (Japan)
2)	K962809	SEIRIN	Seirin Kasei (Japan)
3)	K961339	CARBO	Dynasty Medical (China)

4) Description of the Device:

JIN acupuncture needles are EtO sterilized, surgical grade stainless steel with pyrogen free for single-use only.

JIN needles comply with the GMP quality and safety requirements.

JIN needles use tightly secured metal handle for safe, excellent handling and are easy to use.

5) The intended use for the JIN needles is to pierce the skin in the practice of acupuncture by qualified practitioners as determined by the States.

And the indication for use is to pierce the skin in the practice of acupuncture by qualified practitioners as determined by the States. The device is intended for single use only.

6) The device package will have the following warnings:

A) Caution: Federal law restricts this device to sale by or on the order of qualified practitioners of acupuncture as determined by the States.

B) Discard any unused needles in bulk packages after treatment session.

7) JIN needles, to be sold in America, will in no way differ in quality, materials, or manufacturing from the Japanese needles currently being sold in Japan by TAIHO.

Description of the Device

A) Intended use for the device:

The intended use is for the practice of acupuncture by qualified practitioners as determined by the States.

Each model of JIN needles is used the same way.

B) Packaging:

All JIN needles are packaged in bulk.

C) Brief description of the JIN needles:

Model ST needles (Bulk package): Sterile disposable, surgical stainless steel Japanese acupuncture needle with pressed pipe type metal handle.

5 needles and 1 plastic insertion tube per sterile sealed package separately.

Model PT needles (Bulk package): Sterile disposable, surgical stainless steel press tack is secured within the tape.

Model ID needles (Bulk package): Sterile disposable, surgical stainless steel intradermal skin needles with flat handle.

Comparison to a Legally Marketed Device

A) Comparison Information

Subject-JIN	#1-ITO	#2-SEIRIN	#3-CARBO

1) Intended use: JIN is identical to #1, #2, and #3: "The intended use is for the practice of acupuncture by qualified practitioners as determined by the States."

2) Labeling: JIN is identical to #1, #2, and #3: The label states A) Single Use Sterile Acupuncture Needle, B) "Caution: Federal law restricts this device to sale by or on the order of qualified practitioners of acupuncture as determined by the States", C) Bulk package: "Discard any unused needles in bulk packages after treatment session", D) "Pyrogene Free", E) Package size -

individually or in bulk, F) Model name, size, lot no. and expiration date, G) the origin of product.

3) Specifications: Size and gauge of JIN are very identical to #1, #2, and #3 though there might be slight differences, because Chinese and Japanese gauge systems are not exactly the same

4) Materials: JIN is identical to #1, and #3: Both needle body and handle are made of surgical grade stainless steel but different from #2, SEIRIN uses plastic for the handle.

B) Analysis of the comparable safety and effectiveness:

The comparable safety and effectiveness to the legally marketed devices is demonstrated historically in Japan.

JIN needles (manufactured by TAIHO) are equal or superior in safety and effectiveness to #1, #2, and #3 in use in Japan for over a period of more than 60 years. They enjoy a large market share (over 10 million disposable needles a year) as well as a good reputation that sustains being one of the more expensive needles.

TAHIO pioneered and introduced stainless steel acupuncture needles to Japan in the late 1940's before anyone else.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 1998

Mr. Kunia Suzuki
President
Kenshin Trading Corporation
1815 West 213the Street Suite 180
Torrance, California 90501

Re: K980899
Trade Name: JIN™ Acupuncture Needles, Models ST, GL, SI, PT, and ID
Regulatory Class: II
Product Code: MQX
Dated: May 19, 1998
Received: May 20, 1998

Dear Mr. Suzuki:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Notification
Class II
Product Code: MQX
Panel Code: General Hospital
Single Use Sterile Acupuncture Needles

510(k) Number (if known): K980899

Device Name: Single Use Sterile Acupuncture Needles

Indications For Use:

To pierce the skin in the practice of acupuncture by qualified practitioners as determined by the States. The device is intended for single use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K980899