APR 3 1998

K980469

American Institute of Koryo Hand Therapy, Inc.

3435 Wilshire Blvd., Suite 690, Los Angeles, CA 90010 Tel: (213) 380-5878 Fax: (213) 380-5876

Premarket Notification [510(k) Number]:

510(k) SUMMARY

As Required by 21 CFR 807.92(c)

Trade Name:	KHT Sooji Needle
Common Name:	Hand Acupuncture Needles
Classification Name:	Class II, Single use acupuncture needles

Legally Marketed Device to Which We Are Claiming Equivalence:
CW-Disposable Acupuncture Needle
510(k) Document Number: K962419

Acupuncture needles are defined as prescription devices intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the States.

Acupuncture needles have been used for the general practice of acupuncture in the United States for over 30 years. Since that time, we are not aware of any serious or life threatening accidents involving acupuncture needles.

Acupuncture needles which were sold through commercial interstate distribution prior to May 28, 1976 were non-sterile, reusable acupuncture needles. Acupuncture needles which are currently being marketed through interstate distribution (i.e., 1997) offer greater safety since they are sterilized, single use only acupuncture needles.

The subject of this 510(k) application - the KHT Sooji Needle - is a sterilized, single use only hand acupuncture needle. The design, material used, sterility and biocompatibility of this acupuncture needle meet the general specifications and criteria for an single use acupuncture needle and is effective for the practice of acupuncture.

In conclusion, based on the information provided with this 510(k) application, the KHT Sooji Needle meets the criteria for 510(k) acceptance. The KHT Sooji Needle is equivalent to acupuncture needles which were in commercial distribution prior to May 28, 1976. Also, the KHT Sooji Needle is equivalent to other single use acupuncture needles which are currently being sold through interstate commerce.

Jin Hae Lew, Director

1-22-98
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 1998

American Institute of Koryo Hand Therapy, Incorporated
C/O Mr. George Su
Regulatory Consultant
Crosslinks International
17870 Castleton Street, Suite 265
Industry, California 91748

Re: K980469
Trade Name: KHT Sooji Needle, Hand Acupuncture Needles
Regulatory Class: II
Product Code: MQX
Dated: January 22, 1998
Received: February 6, 1998

Dear Mr. Su:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (21 CFR 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/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

Indications For Use

510(k) Number (if known) _____

Device Name: KHT Sooji Needle, Hand Acupuncture Needle

Indications For Use:

To pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
(D Division of Dental, Infection Control,
D and General Hospital Devices
anc 510(k) Number K980469
510(K

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)