행 림 서 원

杏林書院

HAENG LIM SEO WON SINCE 1923

HAENG LIM CO., LTD

Company Information

COMPANY	HAENG LIM CO., LTD
BRAND	HAENG LIM, TAEKEUK, HAENG LIM SEO WON
CEO	EUL SUB LEE
ITEM	Sterile acupuncture needles / Massage Accessories / Moxa
ADRESS	67, Eunbong-gil, Ganam-eup, Yeoju-si, Gyeonggi-do, 12663, Rep. of KOREA
PHONE	82-31-881-6444
FAX	82-31-881-6445
E-mail	info@hlmedical.com
WEB SITE	WWW.HLMEDICAL.COM

History

1923
Renowned oriental medicine scholar Lee "Haengpa" TaeHo founds Haeng Lim Seo Won in Anguk-dong, Seoul.

1950
Company moves to DongAm-dong, Seoul.

1955
Company moves to GyungWoon-dong, Seoul

1962
Lee TaeHo's son Lee Sung Mo expands business to Jongro-gu, Eunyi-dong.
Store relocated to Jongro 5-ga. Oriental medicine businesses flourish in the neighborhood thereafter.

1972
Lee Sung Mo passes away. His wife, Song Young San becomes president.

1975
Acupuncture manufacture company "Haeng Lim Medical" established.

1991
Haeng Lim Medical changes name to "Haeng Lim Seo Won Medical."
Lee Taeho's grandson, Lee Eul Sub, becomes president.

1992
Company begins to use gamma rays for acupuncture sterilization.

History

1994
Haeng Lim Seo Won Medical's acupuncture becomes the first in Korea to receive the "Q"-mark distinction, indicating high quality standard.

2001
Company relocates from Choonwui-dong, Boochun-shi, Gyeonggi-do, to Gwanyang-dong, Anyang-shi, Gyeonggi-do.
First Korean company to apply ▶ gamma ray sterilization indicator . (color change: yellow → red).

2006
Facility expansion to ganam-myeon, Yeoju-gun, Gyeonggi-do. Headquarters established.

2006
Authorization of KGmp Facility and operation system by KFDA.

2010
Registered FDA 510(k) for disposable acupuncture.

2018
KGmp Facility and Operating System Renewed by KFDA

Haeng Lim Acupuncture Needles

1

HS-CODE	9018.39.0050
Model	HL-001 SERIES
Name	Haeng Lim Acupuncture Needles Gamma-Ray Sterilized

Acupuncture is a technique of inserting and manipulating fine filiform needles into specific points on the body to relieve pain without injection of drugs.

Haeng Lim Acupuncture Long Needles

2

HS-CODE	9018.39.0050
Model	HL-001 SERIES
Name	Haeng Lim Acupuncture Long Needles
Thickness	0.25, 0.30, 0.35, 0.40㎜
Length	75, 90, 105, 120㎜
	Gamma-Ray Sterilized

Acupuncture is a technique of inserting and manipulating fine filiform needles into specific points on the body to relieve pain without injection of drugs.

Special acupuncture needles

Haeng Lim Sujichim / "T" Needles

3

4

Sterile acupuncture needles

HS-CODE	9018.39.0050
Model	YS-001
Name	Haeng Lim Sujichim

NonSterile acupuncture needles

HS-CODE	9019.10.2050
Model	HL-03(T침)
Name	Ear Press "T" Needles

Painless press pellets

5

HS-CODE 7616.99.9090

Name Haeng Lim Press Pellets (#1)

Model Haeng Lim Press Pellets (#6)

Press & Stimuate Acupuncture point to helps blood circulation

Moxibustion

HS-CODE 3004.90.9900

NO.	Moxa Name	Shape	Stick-on	Type	Quantity
1	TaeKeuk Moxa	roll	●	Hot	225pcs/box
2	TaeKeuk Mini Moxa (Red)	pipe	●	Hot	180pcs/box
3	Taekeuk Mini Moxa (Green)	pipe	●	Warm	180pcs/box
4	Smokeless Mini Moxa	pipe	●	Warm	180pcs/box

Stick on, indirect mild moxa. Uniform heat slowy heals discomforted area of the body.

Acupuncture accessories

HS-CODE 1211.90.9190
Lancing Device

10
Lancing Device

11
Lancing Device

12
Lancing Device

13
Massage Roller

HS-CODE 9019.10.2050
Massage accessories

14
Single probe

15
Dual probe

16
Roller Needles

Certificate

KGMP

인정번호(No.) : KCL-ABBA-12481

의료기기 제조 및 품질관리 기준 적합인정서
(Certificate of GMP)

■ 업소명/허가번호 (Company name of Applicant / License No.)

(주)행림/제 372 호
HAENG LIM CO., LTD

■ 업소 소재지 (Company address of Applicant)

경기도 여주시 가남읍 은봉길 67
67 Eunbong-gil, Ganam-eup, Yeoju-si, Gyeonggi-do

■ 제조소명 (Name of Manufacturer)

제 조 자 : (주)행림(HAENG LIM CO., LTD)

■ 제조소 소재지 (Address of Manufacturer)

제 조 자 : 경기도 여주시 가남읍 은봉길 67
67 Eunbong-gil, Ganam-eup, Yeoju-si, Gyeonggi-do

■ 품목군 (Category)

주사기 및 주사침류(Syringe or Needle)

의료기기 제조 및 품질관리기준에 적합함을 인정합니다.
(We hereby certify that the above manufacturer complies with Korea Good Manufacturing Practices of Medical Devices for the product group listed above)

발행일자(Date of Issue) : 2021. 11. 09
유효기간(Date of Expiration) : 2024. 11. 08

KCL (재)한국건설생활환경시험연구원장
Korea Conformity Laboratories

FDA

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -W066-G609
Silver Spring, MD 20993-0002

Haenglim Seowon Medical Company
C/O Ms. Jean Asquith
Senior Regulatory Affairs Consultant
Emergo Group, Incorporated
1705 South Capital of Texas Highway, Suite 500
Austin, Texas 78746

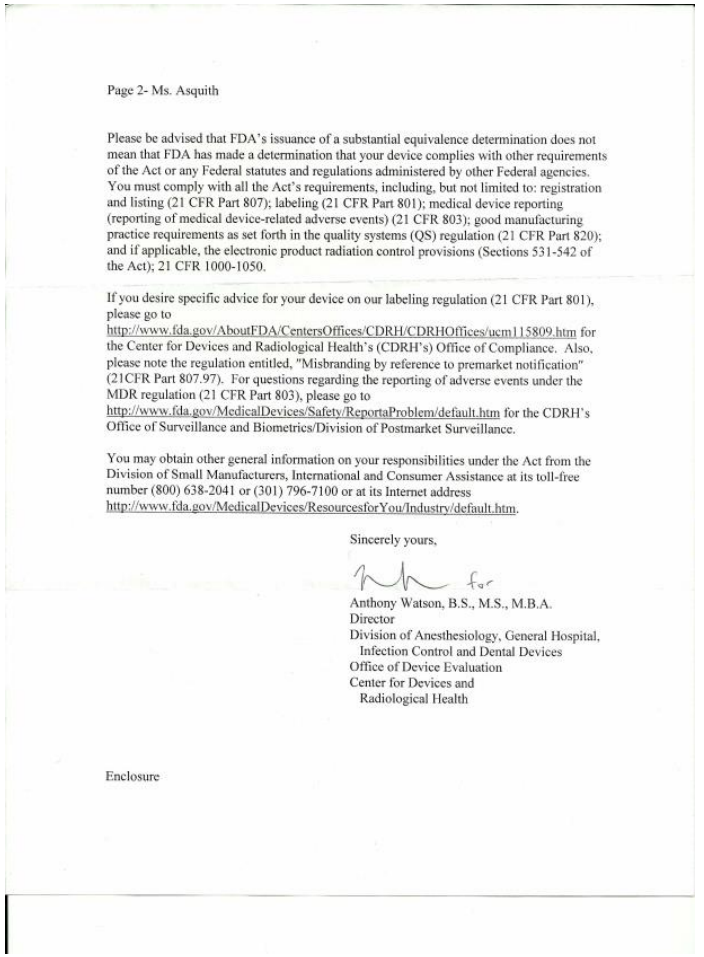
APR 21 2010

Re: K092240
Trade/Device Name: Acupuncture Needles
Regulation Number: 21CFR 880.5580
Regulation Name: Acupuncture Needle
Regulatory Class: II
Product Code: MQX
Dated: March 31, 2010
Received: April 2, 2010

Dear Ms. Asquith:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.



Page 2- Ms. Asquith

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

HAENG LIM CO., LTD