MAY 25 2012

Exhibit 5 **510(k) Summary**

CHOYANG Thermal Massager (Model: CY-7000)

1. Submitter and US Official Correspondent

Submitter: Choyang Medical Instrument Co., Ltd.
Address: 66-3 Yogwang-ri, Chubu-myeon, Geumsan-gun
Chungcheongnam-do, 312-943, Korea
Tel: +82-41-754-8070~3
Fax: +82-41-754-8075
Contact: Jung Hyun, Quality Assurance Manager
Email: jh0158@nate.com

US Official Correspondent: Shin Kuk Yoo, Consultant
Telephone No.: 714-313-7442
Fax No.: 01-303-7455
Email: skyone@LSKBioPartners.com

2. Establishment Registration Number

The firm will be registered and listed prior to distribution of medical device in United States.

3. Device Information

Proprietary/Trade Name:	CHOYANG Thermal Massager (Model: CY-7000)
Common/Usual Name:	Multi-function physical therapy table, Therapeutic massager
Classification Name:	Table, Physical therapy, Multi-function
Product Code:	JFB
Subsequent Product Code:	ISA
Device Class:	Class II per regulation 21 CFR 890.5880, 21 CFR 890.5660

4. New or modification

This notification is for a new device for the USA market.

5. Equivalent Legally Marketed Device

Predicate #1

Manufacturer:	Migun Medical Instrument Co., Ltd.
Device Name:	HY7000 Thermassage Energy Product
510(k) Number:	K041200 (Decision Date – June 17, 2004)
Classification:	Table, Physical Therapy, Multi Function
	JFB (Classification Product Code)
	Class II per regulation 21 CFR 890.5880

Predicate #2

Manufacturer:	CERAGEM Co., Ltd.
Device Name:	CERAGEM-RH1 Automatic Thermal Massager
510(k) Number:	K062476 (Decision Date – Oct. 31, 2006)
Classification:	Table, Physical Therapy, Multi Function
	JFB (Classification Product Code)
	Class II per regulation 21 CFR 890.5880

6. Description of the Device

The CHOYANG Thermal Massager (Model: CY-7000) is an electrically powe red, motorized multi-functional physical therapy table. It is intended function and use is to prov ide patients with muscle relaxation therapy by delivering heat and soothing massage. The massage function is delivered by way of two independent carriages. Each carriage has five infrared lights. During use, these carriages traverse from lower torso to upper torso and apply light pressure as well as heat to the supine user.

7. Indications for use

The intended use of the CHOYANG Thermal Massager (Model: CY-7000) is t o provide patients with muscle relaxation therapy by delivering heat and soothing massage.

8. Safety, EMC and Performance Data

The compliance of the CHOYANG Thermal Massager (Model: CY-7000) has b een satisfied with the applicable requirements of the EN 60601-1, EN 60601-1-2. The tests have been performed by SGS Testing Korea.

9. Safety and Effectiveness, comparison to Predicate

The results of bench and clinical evaluation indicate that the new device is as safe and effective as the predicate devices.

10. Substantial Equivalence Chart

No	Item	CHOYANG Thermal Massager	HY7000 Thermassage Energy Product	Ceragem-RH1 Automatic Massager
1	510K Number	None	K041200	K062476
2	Manufacturer	Choyang Medical Instrument Co., Ltd.	Migun Medical Instrument Co., Ltd.	CERAGEM Co., Ltd.
3	Regulation Number	CFR 890.5880,	CFR 890.5880,	CFR 890.5880,
4	Product code	JFB, ISA	JFB, ISA, ILY	JFB, ISA, ILY
5	Classification	Class II (21CFR 890.5880)	Class II (21CFR 890.5880)	Class II (21CFR 890.5880)
6	Rated input voltage	120V a.c	120V a.c	120V a.c
7	Supply Frequency	50~60Hz	50Hz	60Hz
8	Rated input power	250W	269W	290W
9	Degree of protection	Type BF applied part	Type BF applied part	Type BF applied part
10	Ambient temperature	40 ~70℃	40 ~70℃	30~60℃
11	Weight	64Kg	74Kg	87Kg
12	Safe working load	Max. 150Kg	Max. 150Kg	Max. 140Kg
13	Massage roller	Jade	Geranium Cerramic	Jade
14	Mode Set-Up	Auto Mode Semi-Auto Mode	Auto Mode Semi-Auto Mode	Auto Mode Semi-Auto Mode
15	Remote Buttons	Rubber Pad Type	Rubber Pad Type	Rubber Pad Type
16	Operating time	36min	34min	40min
17	Intended Use	The intended use of the CHOYANG Thermal Massager is to provide patients with muscle	The intended use of the device is to provide patients with muscle relaxation therapy by delivering heat and soothing massage. Additionally, the infrared lamps provide topical heating for;	

		relaxation therapy by delivering heat and soothing massage.	- temporary relief of minor muscle and joint pain and stiffness - the temporary relief of minor joint pain associated with arthritis - the temporary increase in local circulation where applied - relaxation of muscle

11. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided the above comparison table, the Choyang Medical Instrument Co., Ltd. concludes that the CHOYANG Thermal Massager (Model: CY-7000) is safe and effective and substantially equivalent to the predicate devices as described above.

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

MAY 25 2012

Choyang Medical Instrument Co., Ltd.
% LSK BioPartners, Inc.
Mr. Shin Kuk Yoo
8 East Broadway, Suite 611
Salt Lake City, Utah 84111

Re: K111941
Trade/Device Name: Choyang Thermal Massager (Model: CY-7000)
Regulation Number: 21 CFR 890.5880
Regulation Name: Multi-function physical therapy table
Regulatory Class: Class II
Product Code: JFB
Dated: May 15, 2012
Received: May 17, 2012

Dear Mr. Shin Kuk Yoo:

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.

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 Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 4 **Indications for Use**

510(k) number (if known): K111941

Device Name: CHOYANG Thermal Massager (Model: CY-7000)

Indications for Use:

The intended use of the CHOYANG Thermal Massager (Model: CY-7000) is to provide patients with muscle relaxation therapy by delivering heat and soothing massage.

Prescription Use _____ AND/OR Over-The-Counter Use ____X____

(Part 21 CFR 801 Subpart D) (Part 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111941