DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 5, 2016

Nuga Medical Co., Ltd
Jong Soo Lee
Vice President
185, Jiraeul-ro, Jijeong-myeon
Wonju, Gangwon-do 220-821
Republic of Korea

Re: K153054
Trade/Device Name: N5-1
Regulation Number: 21 CFR 890.5880
Regulation Name: Multi-Function Physical Therapy Table
Regulatory Class: Class II
Product Code: JFB, ILY, ISA
Dated: January 4, 2016
Received: January 5, 2016

Dear Jong Soo Lee:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Hoffmann -A

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153054

Device Name
N5-1

Indications for Use *(Describe)*
The intended use of the N5-1 is to provide patients with muscle relaxation therapy by delivering heat and soothing massage. Additionally, it provides topical heating for;
-Temporary relief of minor muscle and joint pain, and stiffness.
- Temporary relief of minor joint pain associated with arthritis.
- The temporary increase in local circulation where applied.
- Relaxation of muscle.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

February 4, 2016

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Sponsor: NUGA MEDICAL Co., Ltd.
  - Address: 185, Jiraeul-ro, Jijeong-myeon, Wonju-si, Gangwon-do, Korea
- Contact Name: Jong Soo Lee/Vice President
  - Telephone No.: +82 33 730 0001
  - Fax No.: +82 33 730 0008
  - Email Address: oky7800@nuga.kr
- Registration Number: 300200626518
- Name of Manufacturer: Same as Sponsor
  - Address: Same as Sponsor

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

- Trade Name: N5-1
- Common Name: Personal Heating Therapeutic Device
- Classification:

Classification Name	1. Multi-Function Physical Therapy Table 2. Massager, Therapeutic, Electric 3. Lamp, Infrared, Therapeutic Heating
Classification Panel	Physical Medicine
Classification Regulation	21 CFR 890.5880, 21 CFR 890.5660 and 21 CFR 890.5500
Product Code	1. JFB 2. ISA 3. ILY
Device Class	II

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4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate device within this submission is shown as follow;

- 510(k) Number: K111329
- Applicant: NUGA MEDICAL Co., Ltd.
- Common Name: Personal Heating Therapeutic Device
- Device Name: NM-7000

There are no significant differences between the N5-1 and the predicate device that would adversely affect the use of the product. It is substantially equivalent to both device in design, operational principles, functions and technological characteristics.

5. Description of the Device [21 CFR 807.92(a)(4)]

The N5-1 Personal Heating Therapeutic Device is the electric multi-function physical energy device. Its use is to provide muscle relaxing therapy to patients via a thermal function and massage and this device consist of the following components:

(1) Main assembly
(2) 5-Ball Projector
(3) Remote Control
(4) Accessories

Inside the main assembly, 7 internal heating roller type ceramics, which can massage from the cervical vertebra to the lumbar, have been installed.

6. Intended Use [21 CFR 807.92(a)(5)]

The intended use of the N5-1 is to provide patients with muscle relaxation therapy by delivering heat and soothing massage. Additionally, it provides topical heating for;

- Temporary relief of minor muscle and joint pain, and stiffness.
- Temporary relief of minor joint pain associated with arthritis.
- The temporary increase in local circulation where applied.
- Relaxation of muscle.

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7. Technological Characteristics [21 CFR 807.92(a)(6)]

The N5-1 is based on a technical feature comparison, the subject device was found to be similar to predicate device with regard to design, function, and technical characteristics.

	Proposed Device	**Predicate Device**
K Number	Not known	K111329
Common name	Personal Heating Therapeutic Device	Personal Heating Therapeutic Device
Model	N5-1	NM-7000
Manufacturer	NUGA MEDICAL Co., Ltd.	NUGA MEDICAL Co., Ltd.
Intended Use	The intended use of the N5-1 is to provide patients with muscle relaxation therapy by delivering heat and soothing massage. Additionally, it provides topical heating for; -Temporary relief of minor muscle and joint pain, and stiffness. - Temporary relief of minor joint pain associated with arthritis. - The temporary increase in local circulation where applied. - Relaxation of muscle.	The intended use of the NM-7000 is to provide patients with muscle relaxation therapy by delivering heat and soothing massage. Additionally, it provides topical heating for; - Temporary relief of minor muscle and joint pain, and stiffness. - Temporary relief of minor joint pain associated with arthritis. - The temporary increase in local circulation where applied. - Relaxation of muscle.
Emission Source	Tourmanium ceramic	Tourmanium ceramic

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Design			
Component		Main assembly (Mat), Auxiliary Heating Part, 5-ball Projector, Remote controller	Mat, Auxiliary mat, 5-ball Projector, 9-ball Projector, Remote controller, Leg heater
Accessory		Outside cover, Projector cover, User manual	Outside cover, Projector cover, User manual
Material	Internal Projector	Ceramic	Ceramic
	External Projector	Ceramic	Ceramic
Technical Specification			
Temperature		40 - 60°C (104 – 140°F)	40 - 60°C (104 – 140°F)
Mode set-up		Manual Mode and Auto Mode 1/2	Manual Mode 1/2 and Auto Mode 1/2/3/4
Safe Working Lode		170 kg	170 kg

The key differences between both devices are (1) the music player function on the remote controller, (2) the size of the main assembly, (3) the list of components (with or without the 9-ball projector and the leg heater), and (4) Mode set-up, and which do not raise any new safety and effectiveness issues.

Non-Clinical Test Summary:

1) Electrical Safety, Electromagnetic Compatibility and Performance:

The N5-1 complies with the electrical safety and electromagnetic compatibility requirements established by the standards AAMI ES60601-1 and IEC 60601-1-2.

- Testing to confirm compliance with the safety requirements of standard AAMI ES60601-1
- Testing to confirm compliance with EMC requirements of standard IEC 60601-1-2

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2) Software Validation:

The N5-1 contains MODERATE level of concern software. Software was designed and developed according to a software development process and was verified and validated.

Software information is provided in accordance with FDA guidance: The content of premarket submissions for software contained in medical devices, on May 11, 2005;

3) Clinical Test Summary:

No clinical studies were considered necessary and performed.

4) Biocompatibility

The N5-1 does not contain any parts which be contacted with the body of patient directly. Therefore the biocompatibility test has not been performed.

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

When compared to the predicate device (K111329), the N5-1 and the predicate are similar, with respect to indications for use and design, function, and technical characteristics.

9. Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification NUGA MEDICAL Co., Ltd., concludes that the N5-1 is substantially equivalent to predicate device as described herein.