September 12, 2024

Nuga Medical Co., Ltd.
Jun Lee
Official Correspondent
185, Jiraeul-ro, Jijeong-myeon
Wonju-si, Gangwon-do 26355
Korea, South

Re: K240168
Trade/Device Name: N7-S
Regulation Number: 21 CFR 890.5880
Regulation Name: Multi-Function Physical Therapy Table
Regulatory Class: Class II
Product Code: JFB, IRP
Dated: September 3, 2024
Received: September 3, 2024

Dear Jun 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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lauren E. Woodard -S

for Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240168

Device Name
N7-S

Indications for Use *(Describe)*
The intended use of the N7-S is to provide patients with muscle relaxation therapy by delivering heatand 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 air massager module of N7-S is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in blood circulation to the treated areas. The air massager module of N7-S stimulates kneading and stroking of tissues by using an inflatable garment.

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.

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510(k) Summary

1. Date Prepared

September 3, 2024

2. Submitter Information & Contact Person

Name of Manufacturer	NUGA MEDICAL Co., Ltd.
Address	185, Jiraeul-ro, Jijeong-myeon, Wonju-si, Gangwon-do, Republic of Korea
Contact Name	Lee Jun Woo/Assistant Researcher
Telephone No.	+82-33-730-0001
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Email Address	nuga227@nuga.kr

3. Trade Name, Common Name, Classification

Common name: Multi-Function Physical Therapy Table

Trade name: N7-S

Classification Description	21 CFR Section	Product Code
Table, Physical Therapy, Multi Function	890.5880	JFB
Massager, Powered Inflatable Tube	890.5650	IRP

As stated in 21 CFR, parts 890.5880, and 890.5650, each of these generic types of devices has been classified as Class II.

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4. Identification of Predicate Device

The identified predicate devices within this submission are shown as follow:

Predicate device A

510(k) Number	K220572
Applicant	CERAGEM Co, Ltd.
Regulation Name	Multi-Function Physical Therapy Table
Trade Name	Ceragem Automatic Thermal Massager
Device Name	CGM MB-1701 & CGM MB-1702

Predicate device B

510(k) Number	K153054
Applicant	NUGA MEDICAL Co., Ltd.
Regulation Name	Multi-Function Physical Therapy Table
Trade Name	N5-1
Device Name	N5-1

N7-S is an updated version of the predicate device B with an addition of a leg massaging feature. Therefore, it is used as a secondary predicate device.

5. Description of the Device

The N7-S is a multi-function physical therapy device offering muscle relaxation through heat therapy and massage.
It has an internal heating unit (smart module), and this module, equipped with four individual heating elements, delivers targeted heat therapy to the cervical, thoracic, and lumbar vertebrae.
An auxiliary heating unit is used for the heating units located on both arms to boost the heating effect.
For more focused heat therapy and massage, 9-ball projector, Abdominal heating pad are also available.
Additionally, it includes an air massager module that features air compression technology to deliver a relaxing and therapeutic massage.

6. Indications for Use

The intended use of the N7-S 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 air massager module of N7-S is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in blood circulation to the treated areas. The air massager module of N7-S stimulates kneading and stroking of tissues by using an inflatable garment.

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7. Determination of Substantial Equivalence

7.1. Multi-Function Physical Therapy Table

Name	Subject device	Predicate device A	Predicate device B	SE decision
Device Name	N7-S	CGM MB-1701 & CGM MB-1702	N5-1	-
Product Code	JFB, IRP	JFB, IRP	JFB, ILY, ISA	-
Manufacturer	NUGA MEDICAL Co., Ltd.	CERAGEM Co, Ltd.	NUGA MEDICAL Co., Ltd.	-
510(k) No.	-	K220572	K153054	-
Indications for use	The intended use of the N7-S 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 air massager module of the N7-S is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in blood circulation to the treated areas. The air massager module of the N7-S stimulates kneading and stroking of tissues by using an inflatable garment.	The intended use of the Ceragem Automatic Thermal Massager, Model CGM MB-1701 & CGM MB-1702 is to provide patients with muscle relaxation therapy by delivering heat and soothing massage. Additionally, it provides topical radiant infrared heat 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 Air Massager (Only CGM MB-1701) is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in blood circulation to the treated areas. The Air Cell Massager stimulates kneading and stroking of tissues by using an inflatable garment.	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.	Same with Predicate device A

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Name	Subject device	Predicate device A	Predicate device B	SE decision
Components	Main Table	Main Table	Main assembly (Mat)	Similar with Predicate device A
	Remote Control	Remote Control	Remote controller	
	9-ball projector	3-Sphere projector	5-ball Projector	
	Abdominal heat pad	Abdominal Vibration Projector	-	
	Power cord	Power cord	-	
	Outer fabric	Outer fabric	-	
	Headrest	Head cushion	-	
	Air Cell Massager	Air Cell Massager	-	
	-	Supporting Mat	-	
	Projector Cover	Projector Cover		
	Auxiliary Heating Part	-	Auxiliary Heating Part	
The subject device includes all external components that predicate device A has. However, the subject device has the following differences: Abdominal Heat Pad: The Abdominal Heat Pad of the subject device is equivalent to the heating function of the Abdominal Vibration Projector of predicate device A. The headrest in the subject device corresponds to the head cushion in the predicate device A. The subject device includes all components that predicate device B has. Auxiliary Heating Unit: Both the subject device and the predicate device B include an Auxiliary Heating Unit in the Main Table Unit. The two devices use the same heating wire. The aforementioned minor differences do not affect the safety and effectiveness of the device.				
Remote Control	Yes	Yes	Yes	Same
Operation Method	Auto / Manual	Auto / Manual	Auto / Manual	Same
Heating Device Voltage	12V	24V	N/A	Different
Heating Device Power	8W	28.8V	N/A	Different
There is a difference in the voltage and power of the heating device between the subject device and the predicate devices. However, while having higher voltage and power than equivalent devices may pose a risk, lower values are safe. Additionally, there is no difference in thermal performance compared to predicate devices, and they are substantially equivalent. Therefore, these differences do not affect safety or efficacy.				

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Name	Subject device	Predicate device A	Predicate device B	SE decision
Temperature Range	- Main Table: 40℃-60℃ (104°F-140°F) -Auxiliary: 30℃-60℃ (86°F-140°F) -External: 30℃-60℃ (86°F-140°F)	-External, Main, Auxiliary: 30℃-60℃ (86°F-140°F)	-External, Main, Auxiliary: 40℃-60℃ (104°F-140°F)	Main Table unit same with predicate device B Auxiliary and External unit same with predicate device A
Extra Overheating Protection	Yes	Yes	Yes	Same
Temperature Sensor	Thermistor	Thermistor	Thermistor	Same
Heating part	Internal projector(Smart module)	Internal projector	Internal projector	Same
	Auxiliary Heating Part	Internal heating element	Auxiliary Heating Part	
	9-ball projector	3-Sphere projector	5-ball Projector	
	Abdominal heat pad	Abdominal Vibration Projector	-	
Mode	10 Automatic Modes 10 Intensive Modes Manual Mode Projector Mode Air Massage Mode	Mode A 16 Modes Intensive Mode Semi-Automatic Mode Semi-Automatic Master Mode Manual Mode Manual Master Mode Abdominal Vibration Projector Mode Air Massage Mode	Manual Mode and Auto Mode	Similar
The foundations for both automatic mode and manual mode are the same. These differences are not significant changes since they are additional features for user convenience and do not raise any questions about safety or effectiveness.				

7.2. The air massager

Name	Subject device	Predicate device A	SE decision
Device Name	N7-S	CGM MB-1701 & CGM MB-1702	-
Product Code	JFB, IRP	JFB, IRP	-
Manufacturer	NUGA MEDICAL Co., Ltd.	CERAGEM Co, Ltd.	-

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Name	Subject device	Predicate device A	SE decision
510(k) No.	-	K220572	-
Output pressure range	30~140 mmHg	48~240 mmHg	Different
Air pressure level	8 levels settings: Level 1 : 30 mmHg Level 2 : 60 mmHg Level 3 : 80 mmHg Level 4 : 90 mmHg Level 5 : 110 mmHg Level 6 : 120 mmHg Level 7 : 130 mmHg Level 8 : 140 mmHg	9 levels settings: Level 1 : 48mmHg Level 2 : 72mmHg Level 3 : 96mmHg Level 4 : 120mmHg Level 5 : 144mmHg Level 6 : 168mmHg Level 7 : 192mmHg Level 8 : 216mmHg Level 9 : 240mmHg	Different
The air pressure levels of the subject device are divided into 8 levels whereas the predicate device's air pressure levels are divided into 9 levels. The minimum and maximum pressure level of the subject is significantly lower than the predicate device, so there is no safety issue concerned and as for the efficacy, it remains valid since its performance has been demonstrated by the performance testing data included in this submission.			
Mode types	Auto/Manual	Sequential/Peristaltic	Similar
Sequential mode of predicate device can be substituted through the Manual mode for each chamber of the subject device, and the Peristaltic mode can be substituted through the function of evenly applying air pressure to each part through the Auto mode of the subject device, with the cycle starting accordingly. So, these similarities do not affect safety and effectiveness.			
Therapy time	15 or 30 minutes	18 minutes	Different
The predicate device applies a maximum pressure of 240 mmHg for a treatment duration of up to 18 minutes, while the subject device employs a maximum pressure of 160 mmHg for a 30-minute treatment. The extended treatment duration does not necessarily impact safety and efficacy. However, despite the lower pressure in the subject device, the longer treatment time requires caution regarding blood pressure elevation. Consequently, precautions for using the Air Massage Mode are provided in User Manual page 6, taking into consideration the differences from the predicate device.			
Deflation time	4~8s	1~10s	Different

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Name	Subject device	Predicate device A	SE decision
The deflation time of the subject device falls within the range of the predicate device, so these differences do not impact safety and efficacy.			
Number of chambers	5 Chambers	4 Chambers	Different
Even though the number of chambers in the subject device differs from the predicate device (having one more chamber), the chamber count only determines the applicable treatment site with subtle differences. Moreover, since the "applicable treatment site" and "usage instructions" of the subject device fall within the same range as the predicate device, these differences do not impact safety and effectiveness.			
Number of treatment mode	3 modes	3 modes	Same

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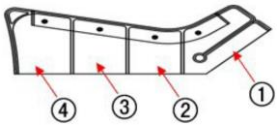
Name	Subject device	Predicate device A	SE decision
Modes (Visual description)	 <Single Chamber Mode> Single Chamber mode operates with the chamber marked in red in the photo above. When the motion starts, the air pressure gradually rises to the set level and then the pressure decreases. When the pressure is reduced, the cycle begins again.  <Dual Chamber Mode> Dual Chamber mode operates with the chamber marked in red in the photo above. When the motion starts, the air pressure gradually rises to the set level and then the pressure decreases. When the pressure is reduced, the cycle begins again.  <Quintuple Chamber Mode> Quintuple Chamber mode operates with the chamber marked in red in the photo above. When the motion starts, the air pressure gradually rises to the set level and then the pressure decreases. When the pressure is reduced, the cycle begins again.	 Mode 1: Starting with the foot chamber and progressing up the thigh chamber, each section compresses and the pressure gradually rises to the pre-determined air pressure level, then decompresses and the air pressure drops. Once the thigh section decompresses, the cycle begins again. Mode 2: Starting with the foot chamber and progressing up the thigh, each section compresses, and the pressure gradually rises to the pre-determined air pressure level, holds the air until the entire garment is compressed. All four sections then decompress simultaneously, and the air pressure drops, then cycle begins again. Mode 3: Start between the foot chamber to the thigh chamber except for No. 4 chamber. And No.4 chamber is compressed while the other chambers are maintained. After that all four sections decompress simultaneously and the air pressure drops, then cycle begins again. This sequence is similar to the Mode 2.	Different
The subject device allows selecting modes for each specific area, while the predicate device offers a mode selection for massaging from the foot to the thigh chamber. However, there is no difference in the way the air pressure drops, and the next cycle begins. Since the treatment area is the same, these differences do not impact safety and effectiveness.			

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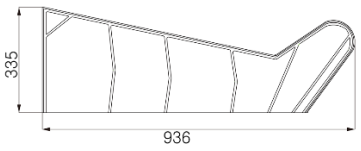
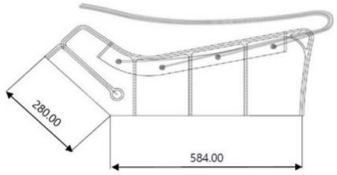
Name	Subject device	Predicate device A	SE decision
Sleeve Material	Oxford and Nylon	Oxford and Nylon	Same
Patient contact	Non-conductive attachments	Non-conductive attachments	Same
Size and appearance of sleeves (leg part)	 One size: 93.6*33.5cm	 One size: 28*58.4cm	Different
Size and appearance of sleeves (leg part): Slight differences of size and appearance of the sleeves do not raise any safety or efficacy issues.			
Safety Features	Power On/off allows user to stop therapy session at any time	Power On/off and mode start/pause button allows user to stop therapy session at any time	Different
The pause function of the predicate device can be replaced with the power-off function in the subject device. This is simply a different type of feature, and both operate as safety features. Therefore, this difference do not raise any concerns regarding safety and efficacy.			
Transportation & Storage environment	Temperature: -25℃ to 70℃ Humidity: 15% to 90% Atmospheric pressure: 700hPa - 1060hPa	Temperature: -20℃ to 60℃ Humidity: 10% to 95% Atmospheric pressure: 500hPa - 1060hPa	Different
The differences in the Transportation & Storage environment do not impact safety and efficacy. It remains valid since its performance has been demonstrated by the Medical Electrical Safety performance testing data included in this submission.			

Based on the test results submitted in this 510(k), we compared N7-S with two predicate devices, CGM MB-1701, CGM MB-1702 (K220572) and N5-1 (K153054). The comparative analysis revealed differences in components, operating modes, and voltage and power of heating devices. However, based on the submitted test results, these differences do not raise any new or different questions about safety or effectiveness.

The Indications for use of the subject device is similar as Predicate Device A and supported by the IFU of Predicate Device B, and the temperature range of the main table unit is the same as that of Predicate Device B, while the temperature range of auxiliary and external unit is the same as Predicate Device A.

The air massager has been compared with both the subject device and the corresponding parts of predicate device A. When comparing the two devices, the two devices have the same in indications for use, patient contact, mode types, and sleeve material, while there are minor differences in detailed operational functions such as air pressure level and therapy time. However, these differences do not significantly impact the safety and efficacy of this air massager part, and the performance related to the differences has been confirmed in the performance test data included in this submission.

In addition, the subject device is equivalent to the predicate devices in terms of indications for use, user interface, functions, and technical characteristics. Therefore, we conclude that the subject device is substantially equivalent to the predicate device.

Non-Clinical Test Summary

Biocompatibility

The N7-S follows the FDA Guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Appendix G, which outlines a least burdensome approach, recommending the inclusion of specific material information in premarket submissions in lieu of biocompatibility testing for these devices. In addition, the cover of the headrest component is identical to that which was cleared in Predicate device B.

This device was tested in accordance with the following standards:

- ES60601-1:2005/(R)2012 A1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2 Edition 4.1 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance
- IEC TR 60601-4-2 Edition 1.0 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

  *Through the above standard, an Immunity performance test was performed and integrated with IEC 60601-1-2.
- IEC 60601-1-11 Edition 2.0 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance
- IEC 62304:2015 Edition 1.1 Medical device software - Software life cycle processes

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Performance Test

A comprehensive performance test was conducted on the subject device, including a pressure performance test of the Air Cell Massager, to substantiate its equivalence to the predicate device A(K220572). The evaluation of the following items revealed that the subject device met all applicable performance requirements and was substantial equivalent with predicate devices.

- Temperature Range
- Extra Overheating
- Protection
- Temperature Sensor function
- Heating part
- Skin surface temperature
- Pressure performance of the Air cell massager

Clinical Test Summary

No clinical studies are considered necessary and performed.

Conclusion

In according with the Federal Food & drug and cosmetic Act, 21 CFR Part 807, and based on the information and documents provided in this premarket notification NUGA MEDICAL Co., Ltd. concludes that the N7-S is substantially equivalent to predicate devices as described herein.