DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 15, 2014

Avacen, Inc.
Thomas G. Muehlbauer, CEO
7920 Silverton Avenue, Suite L
San Diego, CA, 92126

Re: K133981

Trade Name: Avacen 100
Regulation Number: 21 CFR 890.5740
Regulation Name: Powered Heating Pad
Regulatory Class: Class II
Product Code: IRT
Dated: July 17, 2014
Received: July 18, 2014

Dear Mr. Muehlbauer:

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" (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 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,

Felipe Aguel -S

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 on last page.

510(k) Number *(if known)*
K133981

Device Name
Avacen 100

Indications for Use *(Describe)*
The AVACEN 100 is a heat therapy system indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains; muscular relaxation; and the temporary increase of local circulation where applied.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.08.15 04:32:27 -04'00'

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510(k) Summary

General Information

Device	Trade Name:	AVACEN 100
	Common name:	Dry Heat Therapy Device
	Classification name:	Pad, Heating, Powered
	Regulation number:	890.5740
	Product code:	IRT
	Classification panel:	Physical Medicine
	Classification:	Class II device

510(k) Owner: AVACEN, Inc.
7920 Silverton Avenue, Suite L
San Diego, CA 92126
Tel: (888) 428.2236 x 701
Fax: (888) 428.2236

Contact person: Mr. Thomas G. Muehlbauer, CEO

Summary prepared: July 7, 2014

Device Description

The AVACEN 100 consists of a control panel, temperature-controlled raised thermal transfer pad, and a vacuum chamber. The AVACEN 100 is designed to comfortably and noninvasively apply dry heat to the hand for the temporary relief of minor aches and pains. The user places their hand into the AVACEN 100 for approximately 10-30 minutes per treatment session. A vacuum pump creates a slight vacuum (25-35 mm Hg) on the hand, which accelerates the transfer of heat.

Indications for Use

The AVACEN 100 is a heat therapy system indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains; muscular relaxation; and the temporary increase of local circulation where applied.

Predicate Device Information

The AVACEN 100 is substantially equivalent to the following legally marketed predicate device:

Company	Device	510 (k)
Shenzhen Anpan Technology Co., Ltd.	FIR Heat Therapy Systems, Models EH-6601-6612	K111273

A summary of the technological characteristics of the AVACEN 100 and the predicate device is presented in the following table:

Parameter	Anpan FIR Heat Therapy Systems	AVACEN 100	Note
Trade name	FIR Heat Therapy Systems	AVACEN 100	-
Model	EH-6601- 6614	AVACEN 100	-
510(k)	K111273	K133981	-
Manufacturer	Shenzhen Anpan Technology Co., Ltd.	AVACEN, Inc.	-
Date Cleared	November 08, 2011	510(k) Pending	-
FDA Reg	890.5740	Same as FIR Heat Therapy Systems	-
Description as found in 510(k) application	The FIR Heat Therapy System provides heat to the patient's body using infrared technology.	The AVACEN 100 provides heat to the patient's body using subatmospheric pressure.	-
Indications for Use	The FIR Heat Therapy Systems are indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains and minor muscular back pain; muscular relaxation; and the temporary increase of local circulation where applied.	The AVACEN 100 is a heat therapy system indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains; muscular relaxation; and the temporary increase of local circulation where applied.	-
Design principle	Heat therapy	Same as FIR Heat Therapy Systems	-
Heat delivery method	Conduction to skin surface	Same as FIR Heat Therapy Systems	-
Heating Environment	Standard atmosphere	-25 to -35 mm Hg below standard atmosphere	Note 1

Parameter	Anpan FIR Heat Therapy Systems	AVACEN 100	Note
Therapeutic temperature range	40-45°C	40-43°C	Note 2
Approximate skin temperature	41-42°C	Same as FIR Heat Therapy Systems	-
Time to reach maximum temperature	10 minutes	5 minutes	Note 2
Time to reach therapeutic temperature range	5 minutes	3 minutes	Note 2
Recommended treatment time	30-45 minutes	10-30 minutes	Note 2
Maximum Duration per treatment session	45 minutes	30 minutes	-
Patient contacting material	Nylon-cotton blend pad	HDPE	Note 3
Heating element	Carbon fiber	NiChrome wire-wound resistors	-
Device design	Multiple models to fit onto different body parts	Countertop module	Note 4
Electrically powered?	Yes	Yes	-
Power source	6Vdc (4 x "AA" alkaline Batteries)	100-240V, 50-60Hz	Note 5
Operating voltage	6 VDC	12 VDC	Note 5
Leakage Current	N/A	79 uA	Note 6

Note 1: Operation at a slight negative pressure (0.5 to 0.7 psi below standard atmospheric pressure)

Note 2: Difference from predicate device is not significant.

Note 3: Although the patient contacting material of the AVACEN 100 device is different from the predicate device, both materials are considered safe for their intended use and do not raise any safety or effectiveness issues.

Note 4: Although the device design of the AVACEN 100 device is different from that of the predicate device, both of them comply with IEC 60601-1. This difference does not raise any safety or effectiveness issues.

Note 5: The AVACEN 100 device operates from an external power supply that complies with IEC 60601-1. The power supply output is 12 VDC and connects to the AVACEN 100. The predicate device operates from battery power. Since both of the devices comply with IEC 60601-1, this difference does not raise any safety or effectiveness issues.

Note 6: Predicate device is battery powered and has no connector to mains therefore leakage current test is not performed. AVACEN 100 allowed value in normal conditions per IEC 60601-1 is 100uA

The AVACEN 100 uses the same fundamental technology as the predicate device and the same intended uses. The fundamental purpose of both devices is to provide heat to relieve common aches, muscle tightness, strains, etc. There is nothing new in the treatment goal, only variations in getting the heat to the site.

Nonclinical Testing

The AVACEN 100 is in conformity with the following standards and normative documents.

- ANSI/AAMI ES60601-1: Medical Electrical Equipment - Part 1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012
- AAMI/ANSI/IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: Collateral Standard: Electromagnetic compatibility -Requirements and tests (Edition 3): 2007
- AAMI/ANSI/ISO 10993-1: 2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing, Risk Management Process
- AAMI/ANSI/ISO 10993-5: 2009, Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity - Biocompatibility
- ISO 10993-10 3rd Edition 2010-08-01 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.

Conclusion

The AVACEN 100 is substantially equivalent to the predicate device, the Shenzhen Anpan FIR Heat Therapy Systems, their indications for use are essentially the same, they utilize similar technologies, and they meet the same conformance test standards.