



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 23, 2014

Nice Recovery Systems, LLC
c/o Dave Yungvirt, CEO
Third Party Review Group
45 Rockefeller Plaza
Suite 2000
New York, New York 10111

Re: K143197
Trade/Device Name: Nice1
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, ILO
Dated: December 8, 2014
Received: December 9, 2014

Dear Dave Yungvirt,

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,

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

Indications for Use

510(k) Number (if known)

K143197

Device Name

Nice1

Indications for Use (Describe)

The Nice1 combines cold and compression therapies. It is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold and compression are indicated. It is intended to be used by or on the order of a healthcare professional in hospital, outpatient clinics, athletic training settings, or home settings.

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)

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

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Traditional 510(k) Summary as required by Section 21CFR 807.92(c)

Submitter/Owner	Nice Recovery Systems LLC CEO: Michael Ross 1382 Kalmia Avenue Boulder, CO 80304 phone: 1-646-675-7700 fax: 1-720-302-1262
Contact Person	Michael Ross Nice Recovery Systems LLC 1382 Kalmia Avenue Boulder, CO 80304 phone: 646-675-7700 fax: 1-720-302-1262 mr@nicerecovery.com
Date the summary was prepared	December 5, 2014
Name of the Device	Trade Name: Nice1 Common Name: Cold/Compression Therapy System
Classification	Classification Name: Cold water circulating pack/Powered inflatable tube massager Primary Product Code: IRP Secondary Product Code: ILO Class II 890.5650 Physical Medicine
Manufacturing Facility	Sparton Medical Systems Colorado 4300 Godding Hollow Parkway Frederick, CO 80504 Establishment Registration Number: 1724385
Predicate Device	Game Ready System Manufactured by CoolSystems Inc. K071050 Product Code: ILO/IRP Class II Cold water circulating pack/Powered inflatable tube massager

<p>Device Description</p>	<p>Nice1 is a cold and compression therapy device used to aid recovery and reduce pain associated with soft tissue injuries. The device works by circulating cooled water and air through a therapy wrap that is placed on the injured body part. The cooled water circulates through the therapy wrap and provides cold therapy; the air inflates the therapy wrap causing it to compress around the injured body part.</p> <p>The Nice1 uses thermoelectric technology to chill the water.</p> <p>The Nice1 consists of 3 key components:</p> <ol style="list-style-type: none"> 1. The control unit which chills the water and contains the pneumatic system for inflating and deflating the therapy wraps. 2. The hose assembly which connects to the control unit to the therapy wrap and provides conduits for the flow of water and air to and from the therapy wrap. 3. The therapy wrap which is placed on the patient and wraps around the injured body part to deliver cold and compression therapy. <p>The control unit is an electromechanical, software-controlled device housed in a plastic enclosure. The device is approximately 8 x 7.64 x 8” and weighs 10 lbs. Inside the control unit are a thermoelectric heat exchange for cooling the water, a pneumatic system to control the flow of air to/from the therapy wrap to regulate compression, and electronics to control the therapy. Integrated into the plastic enclosure is graphical touch screen that displays outputs and receives inputs from the user. Temperature, compression levels and therapy duration are selected by the user via the graphical touch screen interface and controlled by a microprocessor.</p> <p>The control unit contains a 300ml reservoir that is filled with water by the user. Water from the reservoir is cooled by passing through the thermoelectric heat exchange; it is then pumped from the control unit through the hose assembly, through the therapy wrap and then returns to the control unit to be re-chilled. Temperature is controlled in five (5) levels ranging in temperature from 59°F to 43°F.</p> <p>Compression can be set at low, medium and high settings ranging from 0 mmHg to 75 mmHg. The compression cycles from high to low on 2 – 5 minute intervals to achieve Intermittent</p>
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	<p>Pneumatic Compression.</p> <p>The hose assembly is 6 feet long and consists of a foam rubber outer sheath to provide insulation and 3 urethane tubes that carry water and air to/from the control unit and therapy wrap.</p> <p>The therapy wraps are comprised of 3 layers of urethane coated nylon that are welded together to make 2 separate air and liquid tight layers for the air and water. The therapy wraps are tailored to fit specific body parts. At the current time the company is only marketing a knee wrap. Therapy wraps use a Velcro closure to allow for customized fitting for different patients.</p>
<p>Intended Use</p>	<p>The Nice1 combines cold and compression therapies. It is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold and compression are indicated. It is intended to be used by or on the order of a healthcare professional in hospital, outpatient clinics, athletic training settings, or home settings.</p>
<p>Summary of Technological Characteristics in Comparison to Predicate</p>	<p>Nice1 and Game Ready have substantially equivalent functions:</p> <ul style="list-style-type: none"> -Both devices pump cooled water through a hose and therapy wrap that is placed on the injured body part of the patient. -Both devices inflate and deflate the therapy wrap and regulate air pressure to achieve Intermittent Pneumatic Compression. -Both devices use a microprocessor to control water temperature, compression levels and therapy duration. -Both devices have therapy wraps that correspond to specific body parts. -Both devices use therapy wraps that are comprised of 3 layers of urethane coated nylon that are welded together to make 2 separate air and liquid tight layers for the air and water. <p>Nice1 differs from Game Ready in only 3 significant aspects:</p> <ol style="list-style-type: none"> 1. Nice1 uses thermoelectric technology to cool the water, so the patient only needs to add water to the reservoir. Game Ready uses ice to cool the water, so the patient must fill the reservoir with both ice and water. 2. Because Nice1 and Game Ready use different methods to cool the water (thermoelectric vs. ice) the devices use different water flow rates to maintain the same levels of cold therapy. The differing flow rates are completely transparent to the user as the user is only aware of the cold therapy which is identical regardless of the fact that the water is flowing at different rates inside of the system. 3. Nice1 uses a graphical touch screen to display options and

	<p>messages as well as receive inputs from the user. Game Ready uses physical dials, buttons and a liquid crystal display to display options and messages as well as receive inputs from the user.</p> <p>Both products have substantially equivalent functions and provide equivalent therapies.</p>
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<p>Non-clinical Testing</p>	<p>Nice1 complies with AAMI ANSI ES60601-1:2005/(R)2012, AI:2012 general requirements for electrical safety and IEC 60601-1-2:2007 electromagnetic compatibility.</p> <p>Substantial equivalence with the predicate device is supported by Performance testing. Performance data demonstrates comparable results for cold therapy and compression therapy. A summary of the testing results follows:</p> <ol style="list-style-type: none"> <p>Cold Therapy: The Nice1 and Game Ready operate at similar therapeutic temperatures. The coldest temperature for the Nice1 is 43 degrees F while the coldest temperature for Game Ready is 37 degrees F.</p> <p>The main difference demonstrated in non-clinical testing was that the Game Ready reaches cold temperatures quicker than Nice1 because it uses ice to cool water. Ice has an almost instantaneous effect while the thermoelectric technology used by Nice1 requires a cool-down time of approximately 5 – 10 minutes to reach the target low temperature.</p> <p>Compression Therapy: Compression Therapy: The Nice1 and Game Ready devices both operate at the same compression levels and cycle times.</p> <p>At the High setting: the Nice1 inflated to 75 mmHg for 2.5 minutes and then deflated to 5 mmHg for 1 minute. The Game Ready inflated to 75 mmHg for 2.5 minutes and deflated to 5 mmHg for 1 minute.</p> <p>At the Medium setting: the Nice1 inflated to 50 mmHg for 2.5 minutes and then deflated to 5 mmHg for 1 minute. The Game Ready inflated to 50 mmHg for 2.5 minutes and deflated to 5 mmHg for 1 minute.</p> <p>At the Low setting: the Nice1 inflated to 15 mmHg for 4.5 minutes and then deflated to 5 mmHg for 1 minute. The</p>
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	Game Ready inflated to 15 mmHg for 4.5 minutes and deflated to 5 mmHg for 1 minute.
Conclusions from Non-Clinical Testing	Testing demonstrates that the Nice1 is as safe, as effective, and performs as well as the Game Ready device.
Clinical Testing	No clinical testing data are submitted, referenced or relied on to determine substantial equivalence.
Substantial Equivalence	The Nice1 is substantially equivalent to the Game Ready System, CoolSystems Inc., K071050, Product Code ILO/IRP for cooling and compression based on intended use, design, energy delivered, performance, safety and bench testing.

Similarities and Differences			
Feature	Nice1	Game Ready, K071050 (predicate)	<i>Difference/ Implication</i>
Indication for Use	<p>The Nice1 combines cold and compression therapies. It is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold and compression are indicated.</p> <p>It is intended to be used by or on the order of a healthcare professional in hospital, outpatient clinics, athletic training settings, or home settings.</p> <p>Patient population: Nice1 can be used by adults. And children under 18 can use the device only under the supervision of a licensed healthcare practitioner.</p>	<p>The Game Ready System combines cold and compression therapies. It is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold and compression are indicated.</p> <p>It is intended to be used by or on the order of a healthcare professional in hospitals, outpatient clinics, athletic training settings, or home settings.</p> <p>Patient population: Athletes and active people and surgery patients. Children under 18 can use the device only under supervision of a licensed healthcare practitioner.</p>	<i>Substantially Equivalent</i>
Therapy Temperature Range	Cool: 43°-59°F	Cool: 34°-50°F	<i>Substantially Equivalent</i>
Therapy	Cold / Compression	Cold / Compression	<i>Substantially Equivalent</i>
Mode of	Touch screen. The different	Button, dial with display	<i>The Nice1 uses a touch</i>

Operation	control mechanism does not affect safety and effectiveness.		<i>screen for user interaction as compared to the Game Ready mechanical controls.</i>
Operating Fluid	Tap Water	Tap Water	<i>Substantially Equivalent</i>
Compression Pump Pressure	0-75 mm Hg	0-75 mm Hg	<i>Substantially Equivalent</i>
Electrical Safety	AAMI ANSI ES60601-1 Electrical Safety IEC 60601-1-2 EMC	UL 60601-1 CAN/CSA C22.2 No. 601.1 IEC 60601-1-2:2001	<i>Substantially Equivalent</i>
Compression Setting	<ul style="list-style-type: none"> • Compression Off • Intermittent Compression: -<u>High</u> (5 to 75 mmHg). Approximately 2 to 3 minutes of inflation and 1 minute of deflation. -<u>Medium</u> (5 to 50 mmHg). Approximately 2 to 3 minutes of inflation and 1 minute of deflation. -<u>Low</u> (5 to 15 mmHg). Approximately 4 to 5 minutes of inflation and 1 minute of deflation. 	<ul style="list-style-type: none"> • Compression Off • Intermittent Compression: -<u>High</u> (5 to 75 mmHg). Approximately 2 to 3 minutes of inflation and 1 minute of deflation. -<u>Medium</u> (5 to 50 mmHg). Approximately 2 to 3 minutes of inflation and 1 minute of deflation. -<u>Low</u> (5 to 15 mmHg). Approximately 4 to 5 minutes of inflation and 1 minute of deflation. 	<i>Substantially Equivalent.</i>
Knee Wrap Fit and Dimensions	One size fits all Length: 17” Maximum Circumference: Top: 32” Bottom: 24”	One size fits all Length: 17 3/8” Maximum Circumference: Top: 32” Bottom: 24”	<i>Substantially Equivalent.</i>
Power	AC power 120V~, 50-60 Hz DC input: 15Vdc, 12A	AC power: 100-240 V~, 50-60 Hz DC input: 12Vdc, 2.5A	<i>Substantially Equivalent.</i>