October 29, 2019

CoolSystems®, Inc. (dba Game Ready®)
℅ Natalie J. Kennel
Regulatory Affairs Consultant
NJK & Associates, Inc.
13721 Via Tres Vista
San Diego, California 92129

Re: K192114
Trade/Device Name: Game Ready GRPro 2.1 System
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, ILO
Dated: August 5, 2019
Received: August 6, 2019

Dear Natalie Kennel:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

For Vivek Pinto, Ph.D.
Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192114

Device Name

Game Ready GRPro 2.1 System

Indications for Use *(Describe)*

The Game Ready GRPro 2.1 System 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 licensed healthcare professionals in hospitals, 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary

Sponsor: CoolSystems®, Inc. (dba Game Ready®)
1800 Sutter St. Ste. 500
Concord, CA 94520

Contact Person: Ms. Natalie J. Kennel
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Date Prepared: October 17, 2019

DEVICE INFORMATION:

Proprietary Name: Game Ready GRPro 2.1 System
Common Name: Powered inflatable tube massager
Classification: II
Product Codes: IRP, ILO
Regulations: 21 CFR 890.5650
Classification Panel: 89- Physical Medicine

PRODUCT DESCRIPTION:

The Game Ready GRPro 2.1 System and its accessories including Wraps is a medical device that helps athletes and patients recover from post-surgical and acute injuries to reduce edema, swelling, and pain. The Game Ready GRPro 2.1 System provides cold and compression therapy using ice and water in a portable device. The Game Ready GRPro 2.1 System is a DC-powered, software-controlled device that delivers compressed air and chilled water from the Control Unit through tubing to a Wrap that is designed for a specific body part (e.g., shoulder, elbow, knee, ankle, back) to treat pain and swelling resulting from injuries and/or surgical interventions. The Game Ready GRPro 2.1 System is comprised of the following components:

- Control Unit
- AC Adapter (to convert line power to DC input power)

- Connector Hose (connects Control Unit to the Wrap)
- Optional Carry bag
- Optional Battery Pack (Battery and AC charger)
- Wrap (Sleeve + Heat Exchanger)

INDICATIONS FOR USE:

The Game Ready GRPro 2.1 System 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 licensed healthcare professionals in hospitals, outpatient clinics, athletic training settings, or home settings.

PREDICATE DEVICES:

The selected predicate device, the Game Ready Classic GR2 was cleared on October 31, 2007. CoolSystems® (dba Game Ready) is the owner of the predicate 510(k), K072620.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Table 1 is a detailed comparison of the Game Ready GRPro 2.1 System with its predicate device.

Table 1 Comparison of the Game Ready GRPro 2.1 System and its predicate

Characteristics/ Parameters	GRPro 2.1 (Subject Device)	Game Ready Classic System (GR 2), K072620 (Predicate Device)	Comparison results
Indications for Use	Game Ready GRPro 2.1 System 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 licensed healthcare professionals in hospitals, outpatient clinics, athletic training settings, or home settings.	Game Ready Classic System (GR 2) is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain for which cold and compression are indicated. It is intended to be used by or on the order of licensed healthcare professionals in hospitals, outpatient clinics, athletic training settings, or home settings.	Same; updated to reflect different device name only.
Intended Users	Healthcare professionals, athletic trainers, lay users under the direction of a healthcare professional	Healthcare professionals, athletic trainers, lay users under the direction of a healthcare professional	Same
Intended use environment	Hospitals, outpatient clinics, athletic training facilities, prescription home use.	Hospitals, outpatient clinics, athletic training facilities, prescription home use.	Identical
Principle of Operation	Pneumatic and fluid pumps and flexible multi-chamber wrap deliver intermittent compression and cold therapy.	Pneumatic and fluid pumps and flexible multi-chamber wrap deliver intermittent compression and cold therapy.	Same
Functions			
Cooling Unit/Compressor Description	Small, portable air compressor and ice box packages as one system.	Small, portable air compressor and ice box packages as one system.	Same
Treatment Temperature Range	34 - 50°F	35-50°F	Substantially equivalent. The predicate device could result in a warmer temperature (closer to room temperature due to temperature control mechanism but this doesn't raise different issues of safety and effectiveness. (Highest temperature is limited to room temperature)

Characteristics/ Parameters	GRPro 2.1 (Subject Device)	Game Ready Classic System (GR 2), K072620 (Predicate Device)	Comparison results
Temperature Adjustment Mechanism	Patented fluid flow control technology.	Mechanical valve to control fluid temperature.	Different. Physical mechanism for temperature adjustment is different but the difference results better temperature control. No different issues of safety or effectiveness raised.
Compression levels	Available in three levels: Low (5-15 mm Hg) Medium (5-50 mm Hg) High (5-75 mm Hg)	Available in three levels: Low (5-15 mm Hg) Medium (5-50 mm Hg) High (5-75 mm Hg)	Same
Treatment time adjustment	15 minutes default, increasing or decreasing in 5-minute increments to a max of 90 min or a min of 5 min.	15 minutes default, increasing or decreasing in 5-minute increments to a max of 90 min or a min of 5 min.	Same
Rest Timer	Sleep option	Sleep option	Same
Treatment Cycle	Manual Mode: 15 minutes default, increasing or decreasing in 5-minute increments to a max of 90 min or a min of 5 min. Program Mode: Six (6) pre-programmed treatment on-off cycles are 30-30 or 30-60 min. at no pressure, low pressure, or medium pressure.	Manual Mode: 15 minutes default, increasing or decreasing in 5-minute increments to a max of 90 min or a min of 5 min. Program Mode: Six (6) pre-programmed treatment on-off cycles are 30-30 or 30-60 min. at no pressure, low pressure, or medium pressure.	Same
Software/Software Features	Electronic pressure control and therapy time monitoring. Battery voltage monitoring,	Electronic pressure control, therapy time monitoring, temperature control. Battery voltage monitoring,	Substantially equivalent; subject device uses a different algorithm to adjust water temperature. No different issues of safety or effectiveness raised.
User interface (Control unit control panel)	LCD display and 9 buttons	LCD display and 9 buttons	Substantially equivalent; slightly different temperature display information. Subject devices now displays set point temperature
Number of patients that can be treated at the same time	One	One	Same
Physical Unit			
Dimensions	16.25” L x 7.75” W x 9.25 H (413 x 197 x 235) mm (not including carrying case)	16.25” L x 7.75” W x 9.25” H (413 x 197 x 235) mm (not including carrying case)	Same

Characteristics/ Parameters	GRPro 2.1 (Subject Device)	Game Ready Classic System (GR 2), K072620 (Predicate Device)	Comparison results
Weight	7.3 lbs. (3.31 kgs) empty, Approximately 18 lbs. full of ice and water but less when filled per instructions for use	7.3 lbs. (3.31 kgs) empty, Approximately 18 lbs. full of ice and water	Substantially equivalent. Slight lower weight when filled per instructions for use
Chilling Mechanism	Ice	Ice	Same.
Reservoir Water/Ice Capacity	Approximately 5100 mL (5.4 qt)	Approximately 5100 mL (5.4 qt)	Same.
Coolant	Tap water and ice	Tap Water and ice	Same.
Water flow rate	275-450 mL/min	275-450 ml/min adjustable flow	Substantially equivalent. Both systems have flow rates that provide good temperature distribution. Flow rate is driven by temperature control mechanism on subject device..
Electrical			
Power source	Mains power from medical desktop power supply, optional battery pack	Mains power from medical desktop power supply, optional battery pack	Substantially equivalent, predicate device lists optional battery pack as "under development" Battery is for user convenience only.
Battery Type	Lithium, rechargeable	Nickle-Metal Hydride or Lithium, rechargeable	Substantially equivalent Difference does not raise different issues of safety or effectiveness
Input power	12V 2.5A (through AC adapter)	12V 2.5A (through AC adapter)	Same
Line Voltage	100- 240 V AC	100-240 V AC	Same
Line Frequency	50/60 Hz	50/60 Hz	Same
Electrical Safety and EMC standards met	• ANSI/AAMI ES60601 – 1:2005/(R) 2012 & A1:2012, C1:2009 (R) 2012, A2:2010/(R) 2012- Part 1 • CAN/CSA – C22.2 No. 60601-1:14 Part 1 • IEC 60601-1-6:2010 + A1:2013 • IEC 60601-1-11:2015 • IEC 60601 – 1-2, Ed. 4.0: 2014 BS EN 60601-1-2:2015 • IEC 62366:2007 + A1:2014 • IEC 62133:2012 + C1:2013	• ANSI/AAMI ES60601-1:2005/ IEC 60601-1-2 • EN60601-1-2 compliant (EMC)	Substantially equivalent. Tested subject device meets additional horizontal standards for medical electrical safety and home use; meets 4th edition of EMC standards.

Characteristics/ Parameters	GRPro 2.1 (Subject Device)	Game Ready Classic System (GR 2), K072620 (Predicate Device)	Comparison results
Environment			
Operating Temperature	33.8 – 104 F (1-40 C)	33.8 F – 104 F (1-40C)	Same.
Storage Temperature	33-122 F (1 C – 50 C)	33 F – 122 F (1 C – 50 C)	Same.
Storage Humidity	15% - 90% non-condensing	10% - 95% non-condensing	Substantially equivalent.
Operating Altitude	0-9,843 Ft (3,000 meters)	0-8,000 Ft (0-2,500 m)	Substantially equivalent; subject device range is wider because testing confirmed use up to 3,000 meters.
Wraps (Accessories)			
Wrap technology/characteristics	Flexible "Wraps"; outer sleeve with inner heat exchanger to deliver compression and cold. 2-chamber heat exchanger (water and air).	Flexible "Wraps"; outer sleeve with inner heat exchanger to deliver compression and cold. 2-chamber heat exchanger (water and air).	Same
Wraps Types	Various anatomical wraps in different sizes for: Straight Knee, Straight Elbow, Ankle, Shoulder, Back, Traumatic Amputee, Neck, Lower Limb, Full Leg Boot and Chest	Various anatomical wraps in different sizes for: Straight Knee, Straight Elbow, Ankle, Shoulder, Back	Substantially equivalent. Additional Wraps available since K072620 (predicate) clearance. The new Wraps have same intended use and indications for use as the predicate wraps.
Primary Patient Contacting Material	70 Denier nylon & polyester	70 Denier nylon	Substantially equivalent No different issues of safety and effectiveness
Additional materials for straps and trim (incidental or no patient contact)	Elastomeric materials of nylon or polyester with natural or synthetic rubber/latex	Elastomeric materials of nylon or polyester with natural or synthetic rubber/latex	Same (Elastomeric materials present but not mentioned in predicate device submission)
Biocompatibility	Primary patient contacting components verified as acceptable according to ISO 10993-1 using cytotoxicity, primary irritation and skin sensitization. Additional elastomeric materials were verified as acceptable according to ISO 10993-1 using acute systematic toxicity, primary irritation and skin sensitization.	Primary patient contacting components verified as acceptable according to ISO 10993-1 using cytotoxicity, primary irritation and skin sensitization.	Substantially equivalent. No mention of elastomeric materials biocompatibility in predicate device submission but these materials were in use.
Sterile or Non-sterile	Non-sterile only	Non-sterile only	Same

PERFORMANCE DATA

The Game Ready GRPro 2.1 System with its Wraps has been subjected to design verification and validation testing for electrical safety, electromagnetic compatibility, software V&V, system/bench testing, and storage and transport performance. These tests verified and validated the proper operation of the current version system. All patient contacting components and accessories have been tested to demonstrate appropriate biocompatibility. No part of the system components or accessories are provided sterile or can be sterilized. Cleaning and disinfection instructions have been validated and are included in the labeling for the system and accessories. The Game Ready GRPro 2.1 System with its Wraps has been found to be adequately safe and effective for the intended users, its intended uses, and use environments.

BIOCOMPATIBILITY

The biocompatibility evaluation was conducted within the risk management framework and in compliance with ISO 10993 standards. This evaluation of each device component accessory, specifically the new Wraps, with patient contact included relevant data sources related to biological safety of testing finished device material by supplier, component material history of safe biological use and testing, and use in previously cleared products accessories for the same intended use. This biocompatibility evaluation established the biological safety of the new patient contacting Wraps of the Game Ready GRPro 2.1

CLEANING, DISINFECTION & SHELF LIFE TESTING

Cleaning and disinfection instructions for the non-patient contacting components are given in the labeling. The impact of repeated use of these cleaning/disinfecting materials over the expected life of the Game Ready GRPro 2.1 System Control Unit has been validated.

The Game Ready GRPro 2.1 System uses the previously 510(k) cleared Wraps and new Wraps included in this submission. The Wraps which provide the patient contact are intended for use over intact skin or sterile dressings only. They are provided non-sterile and not intended to be user sterilized. Instructions for how to clean and disinfect if needed the sleeve or heat exchangers of the Wraps have been provided in the respective labeling for the Wraps.

Neither the Game Ready GRPro 2.1 System components nor the Wraps have a definitive shelf life based on packaging or time. Expected life is based on frequency of use and continued functional performance.

SOFTWARE

The software in the Game Ready GRPro 2.1 System, including both custom-developed firmware and OTS software, has been verified and validated and demonstrated to be safe and effective for its intended use. The software is a Moderate Level of Concern (LOC)

per FDA guidance. All required items related to software as required by FDA guidance for moderate LOC have been included in this submission.

ELECTRICAL SAFETY & EMC

The Game Ready GRPro 2.1 System complies with all the medical electrical safety and electromagnetic compatibility requirements of IEC 60601 3.1 edition standards including the ANSI/AAMI/ES60601 with the U.S. deviations, and the 4th edition of collateral standard for EMC. Refer to the list of standards in Table 1.

ANIMAL STUDIES

No animal studies were performed to support this submission.

CLINICAL STUDIES

Although clinical studies were not needed to demonstrate substantial equivalence of the Game Ready GRPro 2.1, the "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices" (July 26, 1995, reformatted 12/18/1997 requires measure of the lowest skin temperature that the device can generate at its lowest setting. This measurement of the lowest skin temperature had to be conducted with healthy volunteer human subjects.

As required by the FDA guidance for heating and cooling devices, the Game Ready GRPro 2.1 System was used at its lowest setting with the worst case wrap and location on healthy subjects. A minimum skin temperature of 41°F was measured and has been included in the product labeling.

CONCLUSION

The data and information provided in this submission support the conclusion that the Game Ready GRPro 2.1 System is substantially equivalent to its predicate device with respect to indications for use and technological characteristics.