January 11, 2021

mks paris
℅ Natalie Kennel
Quality & Regulatory Consultant
NJK & Associates, Inc.
13721 Via Tres Vista
San Diego, California 92129

Re: K193079
Trade/Device Name: ICE COMPRESSION FIRST, DUO, & MOOVE Systems
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP, ILO
Dated: October 9, 2020
Received: October 13, 2020

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193079

Device Name
ICE COMPRESSION FIRST, DUO, & MOOVE Systems

Indications for Use *(Describe)*
The ICE COMPRESSION FIRST, DUO, and MOOVE Systems combine cold and compression therapies. They are intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold and compression are indicated. They are intended to be used by or on the order of licensed healthcare professionals 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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Date Prepared: January 11th, 2021

DEVICE INFORMATION:

Proprietary Name: ICE COMPRESSION FIRST, DUO, & MOOVE Systems
Common Name: Powered inflatable tube massager
Classification: II
Product Codes: IRP, ILO
Regulations: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Classification Panel: 89- Physical Medicine

PREDICATE DEVICES:

The predicate devices are listed in **Table 1**. The primary predicate device is the Game Ready GRPro 2.1 System and the secondary predicate is the Game Ready Med4Elite. The Therm X is the reference device. None of the predicate or reference devices have been subject to design recalls**.**

Table 1 Table of Predicates

510(k)	Product	510(k) Holder	Clearance Date	Scope of safety and effectiveness comparison to subject device
K192114	GRPro 2.1 System	CoolSystems® (dba Game Ready)	October 29, 2019	Compared to all aspects of the subject device. Primary Predicate
K171685	Med4Elite	CoolSystems® (dba Game Ready)	September 29, 2017	Compared to the Duo control module's dual output functionality. Compared to the Wrist Splint and the Hip Splint. Secondary Predicate
K181149	Therm X	Zenith Technical Innovations	August 3, 2018	Compared to the subject device static pressure option. Reference device

PRODUCT DESCRIPTION:

The ICE COMPRESSION **FIRST, DUO, & MOOVE** System and its accessories, including the Splints, is designed to treat post-surgical and acute injuries to reduce edema, swelling, and pain when cold and compression are indicated. The ICE COMPRESSION System provides cold and compression therapy using ice and water. The ICE COMPRESSION System is a DC-powered, software-controlled device that delivers compressed air and chilled water from the Control Module through tubing to a Splint that is designed for a specific body part (e.g.,

shoulder, wrist, knee, leg, hip and ankle, back) to treat pain and swelling resulting from injuries and/or surgical interventions.

The ICE COMPRESSION System is comprised of the following components:

- Control Unit (FIRST, DUO, or MOOVE)
- AC Adapter (to convert line power to DC input power)
- Water/Air Connectors (connects Splint to the Control Module)
- Instruction Manual
- Splints (Accessories)
- Optional Carry Case

The ICE COMPRESSION System Control Unit is available in three variants or models: FIRST, DUO, and MOOVE. The FIRST and the MOOVE models each have only one Splint connection while the DUO has two Splint connectors. The DUO model is essentially the same as the single-splint connection models (FIRST and MOOVE) but with two of the single-splint connection internal models inside one device module. The FIRST and DUO models use the same outside dimensions and different only by whether they contain one or two single-splint connection internal control units. The DUO model can provide therapy to one patient, wearing two splints, or to two patients at the same time. In the DUO model, each of the two single-splint connection models inside, are separately controlled with their own user interface and tank. All three models each use only one Power Supply. The MOOVE model is a smaller more portable unit.

The Water/Air Hose Connector connects the Splint to the Control Module. Water from the Hose Connector fills the Splint's water bladder to provide cold therapy. Air from the Hose Connector fills the air bladder to provide compression. All Splints have both air and water bladders.

INDICATIONS FOR USE:

The ICE COMPRESSION FIRST, DUO, and MOOVE Systems combine cold and compression therapies. They are intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold and compression are indicated. They are intended to be used by or on the order of licensed healthcare professionals in hospital, outpatient clinics, athletic training settings, or home settings.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Table 2 is a detailed comparison of the ICE COMPRESSION FIRST, DUO, & MOOVE Systems with its predicates device.

Table 2 Comparison of the ICE COMPRESSION FIRST, DUO, & MOOVE Systems and its predicates

Characteristics/ Parameters	**ICE COMPRESSION FIRST, DUO, & MOOVE Systems (Subject Device)**	**GameReady GRPro 2.1, K192114 (Primary predicate device)**	**Game Ready Med4Elite, K171685 (Secondary predicate device)**	**Comparison results and reference devices, where applicable**
Indications for Use	The ICE COMPRESSION FIRST, DUO, and MOOVE Systems combine cold and compression therapies. They are intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain where cold and compression are indicated. They are intended to be used by or on the order of licensed healthcare professionals in hospital, outpatient clinics, athletic training settings, or home settings.	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.	The Med4 Elite™ combines cold, heat, contrast and compression therapies. It 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 treat post traumatic and post surgical medical and/or surgical conditions for which localized thermal therapy (hot or cold or contrast) are indicated. It is intended to be used by, or on the order of, licensed healthcare professionals in rehabilitation facilities, outpatient clinics, and athletic training settings.	Substantially equivalent to predicate device; wording differs slightly. Both devices intended to treat the same conditions. Secondary intended use covers the subject device intended use AND additional indications not included in the subject device. Differences between the subject device and the predicate device indications for use do not raise new safety or effectiveness questions.

Contraindications and precautions	Provided in Subject Device User Manual	Available in Predicate Device User Manual	Available in Predicate Device User Manual	Similar, minor wording differences only. Secondary predicate includes contraindications for heat, which does not apply to the subject device.

Characteristics/ Parameters	ICE COMPRESSION FIRST, DUO, & MOOVE Systems (Subject Device)	GameReady GRPro 2.1, K192114 (Primary predicate device)	Game Ready Med4Elite, K171685 (Secondary predicate device)	Comparison results and reference devices, where applicable
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	Healthcare professionals only (prescription use)	Substantially equivalent to primary predicate device; differs from secondary predicate device which is restricted to healthcare professionals
Intended use environment	Hospitals, outpatient clinics, athletic training facilities, prescription home use.	Hospitals, outpatient clinics, athletic training facilities, prescription home use.	Intended for indoor use only such as rehabilitation clinics, outpatient clinics, athletic training settings.	Identical to primary predicate. Differs from secondary predicate which excludes the home use environment.
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.	Pneumatic and fluid pumps and flexible multi-chamber wrap deliver intermittent compression, cold therapy and heat therapy.	Substantially equivalent; secondary predicate description includes heat therapy which is not applicable to subject device
Cooling Unit/ Compressor Description	Small, removable ice water tank(s); no compressor cooling unit.	Small, ice box reservoir; no compressor cooling unit.	Vapor compression cold reservoir unit and resistance heating reservoir unit (1 gallon each).	Similar to primary predicate; ICE COMPRESSION Systems have removable water tank(s). ICE COMPRESSION DUO System has two units in enclosed in one system. Differs from secondary predicate which uses a compressor cooling unit. This does not raise new safety or effectiveness questions.

Characteristics/ Parameters	ICE COMPRESSION FIRST, DUO, & MOOVE Systems (Subject Device)	GameReady GRPro 2.1, K192114 (Primary predicate device)	Game Ready Med4Elite, K171685 (Secondary predicate device)	Comparison results and reference devices, where applicable
Treatment Temperature Range	41-77°F (5-25°C)	34 - 50°F (1- 10°F)	38 – 60°F (3.33-15.56°C) (cold therapy temperature range)	Substantially equivalent. The subject device has a warmer temperature range that does not raise new issues of safety and effectiveness. Highest temperature is driven by the ambient environment (no heating unit in subject or primary predicate).
Water Temperature accuracy	+/-1.8°F (+/-1°C)	+/-4°F (+/-2°C) Per predicate User Manual	+/-4°F (+/-2°C) Per predicate User Manual	Similar. Subject device claims a tighter accuracy than predicate devices; does not raise new issues of safety and effectiveness.
Temperature Adjustment Mechanism	Software adjusts the flowrate based on thermosensor feedback.	Patented fluid flow control technology.	Not publicly available.	Different. Physical mechanism for temperature adjustment is different but both the subject device and the primary predicate use adjustment of water flow rate to controlled by software to adjust temperature. Unable to compare to the secondary predicate. No new issues of safety or effectiveness raised.

Characteristics/ Parameters	ICE COMPRESSION FIRST, DUO, & MOOVE Systems (Subject Device)	GameReady GRPro 2.1, K192114 (Primary predicate device)	Game Ready Med4Elite, K171685 (Secondary predicate device)	Comparison results and reference devices, where applicable
Compression range	0-75 mmHg	5-75 mmHg Or 0 mmHg (no pressure)	5-75 mmHg Or 0 mmHg (no pressure)	Substantially equivalent. Subject device has a lower minimum pressure when oscillating (dynamic mode); Predicate devices can be set to 0 pressure; does not raise different issues of safety and effectiveness.
Pressure Application time	Dynamic pressure: Adjustable from 0-55 seconds of pressure for cycle Static pressure: Up to 45 minutes continuous application of pressure setting	Dynamic pressure: Cyclical compression applied from 5 to 90 minutes (total) in three levels: Low (5-15 mmHg) cycled in 5 minutes Medium (5-50 mmHg) cycled in 3 minutes High (5-75 mmHg) cycled in 3 minutes (per User Manual) No Static pressure	Dynamic pressure: Cyclical compression applied from 5 to 60 minutes (total) with default of 15 minutes in four levels: Low (5-15 mmHg) cycled in 5 minutes Medium-Low (5-30 mmHg) cycled in 3 minutes Medium (5-50 mmHg) cycled in 3 minutes High (5-75 mmHg) cycled in 3 minutes (per User Manual) No Static pressure	Similar for pressure application of dynamic pressure on Subject device compared to predicate devices. Subject device has more flexibility in the cycling timing of pressure. Predicate devices do not have static pressure settings. Reference device K181149 Therm X has a static pressure mode like subject device. Differences do not raise new safety or effectiveness questions because the maximum pressure and range is similar to other devices..
Air Pressure Accuracy	+/- 10mm Hg	+/-10mmHg Per predicate User Manual	+/-10mmHg Per predicate User Manual	Same

Characteristics/ Parameters	**ICE COMPRESSION FIRST, DUO, & MOOVE Systems (Subject Device)**	**GameReady GRPro 2.1, K192114 (Primary predicate device)**	**Game Ready Med4Elite, K171685 (Secondary predicate device)**	**Comparison results and reference devices, where applicable**
Treatment time adjustment	Adjustable from 0- 45 minutes in increments of 1 minute	15 minutes default, increasing or decreasing in 5-minute increments to a max of 90 min or a min of 5 min.	Cold and/or compression therapy: 15 minutes default, increasing or decreasing in 5-minute increments to a max of 60 min or a min of 5 min.	Similar. Subject device maximum treatment time (45 minutes) is less than predicate device maximum treatment time (90 minutes or 60 minutes). Does not raise any different issues of safety and effectiveness. (Cold therapy is limited by use of ice water for subject device and primary predicate device)
Treatment Cycle	Manual Mode: 20 min default, increasing/decreasing in 5-second increments with a minimum of 0 min and a maximum of 45 min.	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.	Cold: 5 to 60 minutes, 1 minute increments Default 15 minutes Compression: 5 to 60 minutes, 15 minutes default	Different: Subject has only manual mode that can be adjusted up to 45 minutes; primary predicate devices pre-programmed treatments are customizable. Secondary predicate settings have adjustable default settings. Differences do not raise new issues of safety or effectiveness raised.
Software/ Software Features	Software controls pressure, displays battery level, monitors and adjusts temperature.	Electronic pressure control and therapy time and temperature monitoring. Battery voltage monitoring,	Electronic pressure control and therapy time and temperature monitoring.	Substantially equivalent; subject device uses a different algorithm to adjust water temperature from proprietary algorithm in predicate devices. No different issues of safety or effectiveness raised.

Characteristics/ Parameters	**ICE COMPRESSION FIRST, DUO, & MOOVE Systems (Subject Device)**	**GameReady GRPro 2.1, K192114 (Primary predicate device)**	**Game Ready Med4Elite, K171685 (Secondary predicate device)**	**Comparison results and reference devices, where applicable**
User interface (Control unit control panel)	LCD touchscreen display and 9 surrounding button keys	LCD display and 9 buttons	LCD touchscreen displays all elements	Substantially equivalent to primary predicate; subject device provides users with an option to use the touchscreen or the keys. Secondary predicate uses only touchscreen.
Number of patients that can be treated at the same time	MOOVE: One FIRST: One DUO: Two	One patient	Two patients	Substantially equivalent. Subject FIRST and MOOVE models have substantially equivalent capabilities to the primary predicate. Subject DUO model is substantially equivalent to capabilities of the secondary predicate.
Dimensions	MOOVE: 11.4” x 9.45” x 15.35” (290 x 240 x 390 mm) FIRST: 12.8” x 18.81” x 15.94” (327 x 478 x 405 mm) DUO: 12.8” x 18.81” x 15.94” (327 x 478 x 405 mm)	9.25” H x 7.75” W x 16.25” L (413 x 197 x 235) mm (not including carrying case)	32.5” L x 24.75” W x 43”H (83 cm L x 63 cm W x 109cm H)	Different. Subject device (all models) is larger than the primary predicate. Both subject and primary predicate device are portable. Subject MOOVE model has a handle like predicate device. Subject device is smaller than the secondary predicate. Does not raise different questions of safety or effectiveness.

Characteristics/ Parameters	ICE COMPRESSION FIRST, DUO, & MOOVE Systems (Subject Device)	GameReady GRPro 2.1, K192114 (Primary predicate device)	Game Ready Med4Elite, K171685 (Secondary predicate device)	Comparison results and reference devices, where applicable
Weight (empty/filled)	MOOVE: 5.5 / 11 lbs. FIRST: 11 / 15.4 lbs. DUO: 13 / 22 lbs.	7.3 / 18 lbs. (approx.)	172 lbs (78 kg)	Similar to the primary predicate; the empty predicate device weighs less than 2 of Subject models. When filled, the primary predicate device weight is in between the Subject FIRST and DUO models. The primary predicate device weighs more when full because of slightly higher capacity. The weight of the secondary predicate is heavier than the subject device as secondary predicate is not intended to be portable. Differences do not raise new safety or effectiveness questions.
Chilling Mechanism	Ice	Ice	Vapor compressor	Same mechanism as primary predicate. Mechanism differs from secondary predicate.
Water/Ice Capacity	FIRST & MOOVE: 2,500 mL DUO: 5,000 mL	Approximately 5100 mL (5.4 qt)	1 gallon (3.8 L) Not applicable as ice is not chilling mechanism.	Similar.: largest subject device model capacity is similar to primary predicate capacity. Secondary predicate capacity is not applicable because ice water is not the chilling mechanism. Differences do not raise new safety or effectiveness questions.

Characteristics/ Parameters	ICE COMPRESSION FIRST, DUO, & MOOVE Systems (Subject Device)	GameReady GRPro 2.1, K192114 (Primary predicate device)	Game Ready Med4Elite, K171685 (Secondary predicate device)	Comparison results and reference devices, where applicable
Coolant	Tap water and ice	Tap water and ice	Distilled water (cooled by vapor condenser)	Same as primary predicate. Secondary predicate uses condenser to provide cooling.
Water flow rate	100-350 mL/min	275-450 mL/min	Not publicly disclosed	Similar. The subject device flow rate is slightly slower than the predicate. For both, the flow rate is driven by temperature control mechanism. User doesn't set or control water flow rate. Does not raise different issues of safety and effectiveness
Power source	Battery; power supply connects battery to mains to charge.	Mains power from medical desktop power supply, optional battery pack	Mains power to control unit	Different. All pass electrical safety; differences do not raise different issues of safety or effectiveness
Battery Type	Nickel-Metal Hydride	Lithium, rechargeable	N/A no battery	Different.Both pass electrical safety; difference does not raise different issues of safety or effectiveness
Input power	12V 1A (through AC adapter)	12V 2.5A (through AC adapter)	1200 VA	Similar. primary Predicate amperage is slightly higher. All pass electrical safety; differences do not raise different issues of safety or effectiveness
Line Voltage	100-240 V AC	100- 240 V AC	100-240 VAC	Same
Line Frequency	50/60 Hz	50/60 Hz	50/60 Hz	Same

Characteristics/ Parameters	ICE COMPRESSION FIRST, DUO, & MOOVE Systems (Subject Device)	GameReady GRPro 2.1, K192114 (Primary predicate device)	Game Ready Med4Elite, K171685 (Secondary predicate device)	Comparison results and reference devices, where applicable
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 60601-1-11:2015 • IEC 60601 – 1-2, Ed. 4.0: 2014	• 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/(R)2012 • CAN/CSA C22.2 No. 60601-1:2014 • Type B	Substantially equivalent. Subject and predicate devices were tested to similar electrical safety and EMC standards. Secondary predicate is not for home use so IEC 60601-1-11:2015 is not applicable. Differences do not raise new safety or effectiveness questions.
Operating Temperature	41 – 104 F (5-40 C)	33.8 – 104 F (1-40 C)	50°F - 90°F (10°C – 32°C)	Similar. Differences do not raise new safety or effectiveness questions.
Operating Humidity	15-90%, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa	Not stated in User Manual	30 to 90%, Non-condensing	Subject device has acceptable operating humidity range for indoor use. Subject device range similar to secondary predicate. Differences do not raise new safety or effectiveness questions.
Max Operating Altitude	6,562 Ft (2,000 meters)	9,843 Ft (3,000 meters)	9,842 Ft (3,000 meters)	Similar. Subject device cannot be used at as high an altitude as predicate devices. Differences do not raise new safety or effectiveness questions.

Characteristics/ Parameters	ICE COMPRESSION FIRST, DUO, & MOOVE Systems (Subject Device)	GameReady GRPro 2.1, K192114 (Primary predicate device)	Game Ready Med4Elite, K171685 (Secondary predicate device)	Comparison results and reference devices, where applicable
Storage Conditions	-13 to 95°F (-25 to 35°C) at a relative humidity up to 90%, non-condensing; >95 – 158°F (>35C – 70°C) at water vapor pressure up to 50 hPa	33-122 F (1 C – 50 C) Relative humidity of 15-90%, non-condensing	33°F - 122°F (1°C to 50°C) Relative humidity of 30 to 90%, Non-condensing	Similar. Subject device storage temperature range is wider than the predicate devices. Differences do not raise new safety or effectiveness questions.
Splint/Wrap technology/characteristics	Splint outer cover holds a water bladder and a separate air bladder in place to provide cold and compression therapy. Splint connects to the water circuit and the air circuit.	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).	Substantially equivalent. Splint/wrap delivers ice water and air to provide cold and compression therapy. Primary and secondary predicates use the same wrap design. Differences do not raise new safety or effectiveness questions.
Splints/Wraps Types	Various anatomical wraps in different sizes for: Ankle, shoulder, back, leg, articulated knee, hip, wrist.	Various anatomical wraps in different sizes for: Ankle, Shoulder, Back, Straight Knee, Straight Elbow, Traumatic Amputee, Neck, Lower Limb, Full Leg Boot and Chest	Various anatomical Wraps in different sizes for: Straight Knee, Articulated Knee, Elbow, Ankle, Shoulder, Back, Hip-Groin, Hand-Wrist, Flexed Elbow, Half-leg boot	Overlapping areas/wraps with primary predicate: Ankle, shoulder, back, knee (straight/articulated) and lower limb/leg Overlapping areas/wraps with secondary predicate: Hip and wrist
Primary Patient Contacting Material	Nylon 210 & non-woven polyester	70 Denier nylon & polyester	70 Denier nylon & polyester	Substantially equivalent. Patient contact materials are same types of fabric. No different issues of safety and effectiveness.

Characteristics/ Parameters	ICE COMPRESSION FIRST, DUO, & MOOVE Systems (Subject Device)	GameReady GRPro 2.1, K192114 (Primary predicate device)	Game Ready Med4Elite, K171685 (Secondary predicate device)	Comparison results and reference devices, where applicable
Biocompatibility	Primary patient contacting components verified as acceptable according to ISO 10993-1 using cytotoxicity, primary irritation and skin sensitization.	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.	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-12	Substantially equivalent. Subject device does not contain elastomeric materials. No different issues of safety and effectiveness.
Sterile or Non-sterile	Non-sterile only	Non-sterile only	Non-sterile only	Same
Control Module Expected Lifetime	5 years	5 years	5 years	Same
Parts and Accessories Expected Lifetime (includes splints/wraps)	3-24 months, depending on use	3-24 months, depending on use	3-24 months, depending on use	Same

PERFORMANCE DATA

The Sponsor subjected the ICE COMPRESSION FIRST, DUO, & MOOVE Systems System to design verification and validation testing for electrical safety, electromagnetic compatibility, software V&V, system/bench testing, and biocompatibility. 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 are justified and are included in the labeling for the system and accessories. Therefore, the ICE COMPRESSION FIRST, DUO, & MOOVE System with its Splints are 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 device evaluation included relevant data sources related to biological safety of finished device testing, component material history of safe biological use and testing, and where applicable, safe previous use in other cleared products. This biocompatibility evaluation establishes the biological safety for the splints of the ICE COMPRESSION SYSTEM.

CLEANING, DISINFECTION & SHELF LIFE TESTING

The Sponsor provides the ICE COMPRESSION FIRST, DUO, & MOOVE Systems and system accessories, including the Splints as non-sterile. The ICE COMPRESSION FIRST, DUO, & MOOVE Systems Control Module and system accessories, excluding the Splints, are not patient contacting and have only incidental patient or user contact at most. The user contacts the Splints when setting up or stopping therapy. The unit is not intended for use in a sterile environment. The Sponsor provides cleaning and disinfection instructions in the Instructions Manual.

The ICE COMPRESSION FIRST, DUO, & MOOVE System Splints contact the patient and are intended for use over intact skin or sterile dressings only. The Splints are provided non-sterile and not intended to be user sterilized. The Sponsor provides cleaning and disinfection instructions in the device Instruction manual and in the respective Splint instruction manual.

The expected service life for the systems and splints expected to be five years and 3-24 months based on frequency of use and continued functional performance.

SOFTWARE

The software in the ICE COMPRESSION FIRST, DUO, & MOOVE Systems, including both custom-developed firmware and OTS software, was 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 software items required by FDA guidance for moderate LOC are included in this submission.

ELECTRICAL SAFETY & EMC

The ICE COMPRESSION FIRST, DUO, & MOOVE Systems 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 2.

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 ICE COMPRESSION FIRST, DUO, & MOOVE Systems, the "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices" (July 26, 1995), reformatted 12/18/97 requires measure of the lowest skin temperature that the device can generate at its lowest setting. This measurement of the lowest skin temperature was conducted with healthy volunteers.

As required by the FDA guidance for heating and cooling devices, the ICE COMPRESSION FIRST, DUO, & MOOVE Systems was used at its lowest setting with the worst-case splint and location. A minimum skin temperature of 11.7°C (53°F) was measured and has been included in the product labeling.

Further, the ICE COMPRESSION System treatment temperature range and pressure settings are substantially equivalent to the predicate device. The ICE COMPRESSION System Splints have the same anatomical coverage as the predicate and reference devices.

CONCLUSION

The data and information provided in this submission support the conclusion that the ICE COMPRESSION FIRST, DUO, & MOOVE Systems is substantially equivalent to its predicate devices with respect to indications for use and technological characteristics.