May 29, 2026

Avanutri Equipamentos DE Saúde
% Bruno Milhoci
Consultant
Bhp Consulting, LLC
Rua Santo Antônio, Nº 2262
Tres Rios, RJ 25820-185
Brazil

Re: K252396
Trade/Device Name: Cryo Sport 2.0 (AVA 501)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: May 5, 2026
Received: May 5, 2026

Dear Bruno Milhoci:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
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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.

Submission Number *(if known)*

K252396

Device Name

Cryo Sport 2.0 (AVA 501)

Indications for Use *(Describe)*

The Cryo Sport 2.0 combines cold and compression therapies. It is intended to treat post-surgical and acute injuries to reduce edema, swelling and pain for which cold and compression is indicated. It is intended to treat post-traumatic and post-surgical medical and/or surgical conditions for which localized thermal therapy 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.

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

510(k) Number: K252396 **Prepared on:** May 20, 2026

Contact Details *21 CFR 807.92(a)(1)*

Applicant

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Device Name *21 CFR 807.92(a)(2)*

Device Trade Name	Cryo Sport 2.0 (AVA501)
Common Name	Powered inflatable tube massager
Classification Name	Massager, Powered Inflatable Tube
Regulation Number	21 CFR 890.5650
Product Code(s)	IRP, ILO
Regulatory Class	Class II
Classification Panel	Physical Medicine (89)

Legally Marketed Predicate Devices *21 CFR 807.92(a)(3)*

510(k) #	Trade Name (Primary listed first)	Owner / Sponsor	Product Code
K171685	**Med4 Elite™ (Primary Predicate)**	CoolSystems, Inc. (dba Game Ready)	IRP, ILO

None of the predicate devices listed above have been subject to design recalls.

Device Description Summary *21 CFR 807.92(a)(4)*

The Cryo Sport 2.0 (Model AVA501) is a portable, AC/DC-powered physiotherapy device that combines cryotherapy (cold water therapy) with adjustable pneumatic compression for the treatment of musculoskeletal injuries, post-surgical recovery, and acute soft tissue conditions. The device circulates cooled water through a flexible wrap applied to the affected anatomical area, simultaneously delivering controlled compression via an integrated air compressor.

The system consists of three primary components: (1) a Water Circulation Unit (WCU) housing the reservoir, water pump, air compressor, control electronics, and internal lithium-ion battery; (2) a Connection Hose linking the WCU to the wrap; and (3) a flexible Wrap (heat exchanger sleeve) applied directly to the patient's body part. The WCU incorporates a 2.8-inch color LCD control panel with push-button controls for treatment time, compression pressure, water flow rate, and session start/pause.

Cooling is achieved by filling the reservoir with ice and distilled or filtered water. The circulating cold water extracts heat from the treated tissue via the wrap. Temperature is modulated by adjusting the ice-to-water ratio. Compression is delivered via an integrated pneumatic pump that inflates the wrap bladder to the selected pressure level, in continuous or intermittent mode.

Key Technical Specifications

- Supply voltage: 110–220 VAC, 50/60 Hz (external 12 VDC / 4.0 A adapter)
- Internal battery: 11.1 V, 4400 mAh lithium-ion (approx. 4 hours autonomy)
- Treatment time: 0–120 minutes (5-minute increments); Default: 30 minutes
- Compression range: 0–75 mmHg (continuous and intermittent modes)
- Water flow settings: Low / Medium / High (53–64 L/h)
- Dimensions (WCU): 449 mm x 102 mm x 215 mm; Weight: 5.0 kg (system, without water/ice)
- Electrical classification: Class II, Type B applied part (IEC 60601-1)
- Operating conditions: 0°C to 40°C, 30–90% RH non-condensing

The device is intended for use in professional healthcare environments under the supervision of a licensed healthcare professional. It is not intended for home use and is classified as Prescription Use Only.

Intended Use / Indications for Use *21 CFR 807.92(a)(5)*

Indications for Use Statement

The Cryo Sport 2.0 combines cold 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 cold thermal therapy is 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.

Prescription Use Only (21 CFR 801 Subpart D).

Indications for Use Comparison with Predicate

The Cryo Sport 2.0 and the predicate device Med4 Elite™ (K171685) share the same fundamental intended use: both devices are indicated for the treatment of post-surgical and acute musculoskeletal injuries through the delivery of cold therapy and pneumatic compression to reduce edema, swelling, and pain. Both devices are intended for use exclusively by licensed healthcare professionals in professional rehabilitation and clinical settings, and both are Prescription Use Only.

The primary difference in indications for use is that the Med4 Elite™ additionally offers heat therapy and contrast (alternating hot/cold) therapy, while the Cryo Sport 2.0 is limited to cold and compression therapy. This represents a narrower scope of indications — the Cryo Sport 2.0 indications are a proper subset of the predicate's cleared indications. The absence of heat and contrast therapy modalities does not broaden the indicated population, change the indicated anatomical areas, or introduce any new patient safety considerations.

Based on the comparison above, the indications for use of the Cryo Sport 2.0 are substantially equivalent to those of the predicate device.

Technological Comparison *21 CFR 807.92(a)(6)*

The Cryo Sport 2.0 and the Med4 Elite™ (K171685) are both Class II physiotherapy devices indicated for cold and compression therapy. Both devices deliver cold water through a flexible wrap applied to the patient's body via a circulating pump system, and both incorporate an air compressor to deliver adjustable pneumatic compression. The core therapeutic mechanism is identical between subject and predicate.

The table below provides a complete comparison of all key technological characteristics, identifying differences and providing justification that no new safety or effectiveness concerns are raised:

Characteristic	Cryo Sport 2.0 (AVA501) [Subject Device]	Med4 Elite™ (K171685) [Predicate Device]	Comparison and Justification
1. Indications for Use (IFU)			
Intended Use	"The CRYO SPORT 2.0 system combines cold and compression therapy. 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	Combines cold, heat, contrast, and compression therapies. Intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain for which cold and compression are indicated. Intended to treat post-	The Cryo Sport 2.0 shares the same core intended use as the predicate: cold and compression therapy for post-surgical and acute injuries in a professional healthcare setting. The predicate additionally provides heat and contrast therapy; the Cryo Sport 2.0

	intended to treat post-traumatic and post-surgical conditions for which localized cold therapy is indicated."	traumatic and post-surgical medical and/or surgical conditions for which localized thermal therapy (hot, cold, or contrast) are indicated. Intended for use by licensed healthcare professionals in rehabilitation facilities, outpatient clinics, and athletic training settings. Prescription use only.	does not include these modalities, making it a subset of the predicate's indications. The absence of heat/contrast therapy does not raise new safety concerns since the device is limited in scope. Both devices are prescription-only and intended for the same user population and use environment. The IFU is substantially equivalent.
Intended Users	Licensed healthcare professionals only (prescription use only).	Licensed healthcare professionals only (prescription use only).	Identical — substantially equivalent.
Use Environment	Indoor professional healthcare facilities: rehabilitation clinics, outpatient clinics, athletic training settings. Not suitable for home use.	Indoor professional healthcare facilities: rehabilitation clinics, outpatient clinics, athletic training settings.	Identical — substantially equivalent.
2. Cooling System			
Cooling System Type	Ice-based system: requires ice and water placed in an onboard reservoir. Water is chilled by the ice and circulated through the wrap. Temperature is controlled by the user-adjusted water-to-ice ratio. Thermometer reading range: 1°C to 40°C.	Vapor compression (refrigeration) system. Two separate onboard reservoirs (cold and hot), each 1 gallon (3.8 L). Cold reservoir range: 34–50°F (1.1–10°C). Device maintains temperature automatically without ice.	The Cryo Sport 2.0 uses ice to chill water, while the predicate uses vapor compression refrigeration. Both systems generate cold water that is circulated through a wrap applied to the patient. The functional outcome is equivalent — cold water therapy applied via a wrap. The ice-based approach is well-established in clinical cold therapy (e.g., Game Ready Classic GR2, K072620, also uses ice). The difference in cooling mechanism does not raise new safety or effectiveness concerns.
Coolant / Fluid	Filtered or distilled water with ice.	Distilled water (cold reservoir); distilled water (hot reservoir).	Both devices use water as the circulating medium. No safety impact from this difference.
Temperature Range (Cold)	Temperature depends on ice/water ratio. Thermometer reads 1°C–40°C. Clinical literature guidance: greatest benefit in 4.5°C–15.5°C range.	Cold reservoir set-point range: 34–50°F (1.1–10°C).	Both devices deliver cold water in a clinically relevant range. The Cryo Sport 2.0 temperature is user-controlled (ice ratio), consistent with other ice-based predicates (e.g., K072620). No new safety concerns.

3. Chilling Mechanism			
Chilling Mechanism	Ice. The reservoir is filled with water and ice by the operator. The melting ice chills the water, which is then pumped through the wrap to deliver cold therapy.	Vapor compression (mechanical refrigeration unit). An onboard compressor automatically maintains the set cold temperature without ice.	The technological approach differs (ice vs. vapor compression), but both produce chilled water for circulation through the wrap. Ice-based cold therapy is well-established and safe. The primary predicate device (Game Ready Classic, K072620) also uses ice as its chilling mechanism, confirming substantial equivalence. No new issues of safety or effectiveness are raised.
Heating Mechanism	Not applicable — no heat therapy function.	Resistance heaters (hot water reservoir, set-point range: 95–113°F / 35–45°C).	The Cryo Sport 2.0 does not offer heat therapy and therefore does not require a heating mechanism. Deliberate design choice consistent with the device's cold-and-compression-only indications for use. No safety concern.
4. Power Source			
Mains Power Supply	External AC/DC adapter: input 110–220 VAC, 50/60 Hz; output 12 VDC, 4.0 A (42 VA max). Power supply provided by manufacturer.	Direct AC power: 100–240 VAC, 50/60 Hz. Large internal electronics including compressor, resistance heaters, pumps, and touch-screen computer.	Both devices accept universal input voltage and operate at 50/60 Hz. The Cryo Sport uses a low-voltage external adapter (12 VDC), which reduces electrical risk at the device level. The lower power design (42 VA maximum) is an improvement in electrical simplicity, not a safety concern.
Battery (Internal)	Yes — Lithium-ion battery (11.1 V nominal, 4400 mAh, ~48.84 Wh). Provides approximately 4 hours of operation. Charging time: ~3 hours. Enables cordless / portable use.	No internal battery. AC power required at all times.	The Cryo Sport 2.0 includes an internal rechargeable battery to enable portable/cordless operation. The predicate does not have this feature. The addition of a battery does not raise safety concerns — the battery (LYS 18650 lithium cell) is a standard component, and the device complies with IEC 60601-1 for battery-powered operation. This feature adds user convenience without affecting the therapeutic function or safety profile.
Electrical Safety Classification	Class II equipment, Type B applied part (IEC 60601-1). IPX0.	Class II equipment, Type B applied part (ANSI/AAMI ES60601-1:2005/(R)2012; CAN/CSA C22.2 No. 60601-1:2014).	Both devices are Class II, Type B — substantially equivalent. Both comply with IEC 60601-1 (3rd edition) and its national deviations.

5. Technical Standards Compliance			
Electrical Safety	IEC 60601-1: Medical electrical equipment — General requirements for basic safety and essential performance (3rd edition and applicable national deviations).	ANSI/AAMI ES60601-1:2005/(R)2012; CAN/CSA C22.2 No. 60601-1:2014 (U.S. and Canadian national deviations of IEC 60601-1 3rd edition).	Both devices comply with IEC 60601-1 (3rd edition) and applicable national variants. Substantially equivalent.
Electromagnetic Compatibility	IEC 60601-1-2: Electromagnetic disturbances — Requirements and tests.	IEC 60601-1-2 (collateral standard for EMC, as required by IEC 60601-1 3rd edition).	Both comply with IEC 60601-1-2 for EMC. Substantially equivalent.
Biocompatibility	ISO 10993-1: Biological evaluation of medical devices. Patient-contacting components evaluated per applicable ISO 10993 parts (-5, -10, -12).	ISO 10993-1, -5 (cytotoxicity), -10 (sensitization), -12. Wraps and connector hose exteriors tested and found biocompatible.	Both devices evaluate biocompatibility per ISO 10993-1 framework. The Cryo Sport wraps are surface devices contacting intact skin; the same biocompatibility approach applies as for the predicate. Substantially equivalent.
Quality Management System	ISO 13485: Medical devices — Quality management systems. 21 CFR Part 820 (FDA Quality System Regulation).	21 CFR Part 820 (FDA Quality System Regulation) / ISO 13485.	Both devices operate under a compliant quality management system. Substantially equivalent.
Software	Firmware Version AVA501 V.1.0.0. Controls timing, pressure, and flow. Moderate level of concern (per FDA software guidance).	Software-controlled multimodality device with touch-screen interface. Moderate level of concern per FDA guidance. Full software V&V submitted.	Both devices contain embedded software controlling therapy delivery. Both classified as Moderate Level of Concern. No new safety concerns from software differences.
6. Physical Characteristics			
Dimensions	Water Circulation Unit: 449 mm (L) x 102 mm (W) x 215 mm (H). Compact portable form factor. Supplied with carrying bag.	83 cm (L) x 63 cm (W) x 109 cm (H). Large floor-standing unit with caster wheels.	The Cryo Sport 2.0 is significantly more compact than the predicate. The size difference is attributable to the predicate's dual-patient capability, onboard refrigeration/heating system, and larger water reservoirs. The Cryo Sport is designed for single-patient use with ice-based cooling, requiring no large mechanical systems. The difference in size does not affect safety or clinical performance.
Weight	5.0 kg (water circulation unit + wrap + hose + power supply + cable, without water/ice). Portable.	78 kg (172 lbs). Non-portable; unit has caster wheels for repositioning.	The Cryo Sport 2.0 is substantially lighter, reflecting its portable, single-patient, ice-based design. The weight difference does not affect the therapeutic function (cold/compression

			delivery via wrap). Portability is a design feature, not a safety concern. The lightweight design may reduce ergonomic risk for operators.
Mobility	Stationary during use (stable surface required), but portable — can be carried to different locations. Supplied with carrying bag.	Clinic-stationary unit on caster wheels. Not designed for portability outside the clinical setting.	Both devices are intended for use in a fixed position during operation. The Cryo Sport's portability allows transport between settings. No safety impact.
Number of Patients	Single-patient use.	One or two patients simultaneously, or two anatomical locations on one patient.	The Cryo Sport 2.0 treats one patient at a time, consistent with its design as a single-channel device. The predicate's dual-patient capability is an additional feature not claimed by the Cryo Sport. This difference does not raise safety concerns — it is a scope limitation, not a technological deficiency.
Chilling Reservoir Capacity	Single reservoir for ice and water (user-filled). Filled to labeled fill line. Consumables: ice and filtered/distilled water.	Cold reservoir: 1 gallon (3.8 L). Hot reservoir: 1 gallon (3.8 L). Iceless — filled with distilled water.	Both devices hold sufficient fluid for a standard therapy session. The Cryo Sport replenishes cold by adding ice; the predicate maintains temperature via mechanical refrigeration. No safety difference.
7. Compression Levels and Settings			
Compression Available	Yes — intermittent and continuous pneumatic compression via wrap.	Yes — intermittent pneumatic compression via wrap.	Both devices deliver compression therapy through wraps applied to the body. Substantially equivalent.
Compression Pressure Levels	No pressure — 0 mmHg Low (continuous) — 25 mmHg Average (continuous) — 50 mmHg High (continuous) — 75 mmHg Low (intermittent) — 25/12.5 mmHg (30s on/off) Average (intermittent) — 50/25 mmHg (30s on/off) High (intermittent) — 75/37.5 mmHg (30s on/off) Range: 0–75 mmHg. Resolution: 25 mmHg. Accuracy: ±25%.	Low: 5–15 mmHg Medium-Low: 5–30 mmHg Medium: 5–50 mmHg High: 5–75 mmHg (No-compression option also available)	Both devices offer compression pressure levels up to a maximum of 75 mmHg. The Cryo Sport 2.0 provides both continuous and intermittent compression modes with discrete preset levels (0, 25, 50, 75 mmHg), while the predicate offers a variable range (5–75 mmHg) across four levels. Both devices offer equivalent maximum pressure (75 mmHg) and include a no-compression option. The discrete preset structure of the Cryo Sport simplifies clinical use and does not raise new safety concerns. Maximum compression of 75 mmHg is consistent

			with both the primary and secondary predicates.
Compression Mode	Both continuous and intermittent modes available. Intermittent: 30 seconds on at set pressure, 30 seconds at 50% of set pressure.	Intermittent pneumatic compression (IPC). Compression cycle not specified in 510(k) summary.	The Cryo Sport 2.0 explicitly supports both continuous and intermittent compression, providing greater clinical flexibility. This does not raise new safety concerns — similar modes are present in referenced devices (e.g., VascuTherm, K061866). No safety impact.
8. Treatment Time			
Cold Therapy Treatment Time	Adjustable: 0 to 120 minutes. Resolution: 5-minute increments. Default: 30 minutes.	5 to 60 minutes. Default: 15 minutes.	The Cryo Sport 2.0 allows up to 120 minutes of cold therapy, which exceeds the predicate's 60-minute maximum. The extended time range is consistent with clinical practice guidelines for cold therapy (literature recommends up to 30 minutes per session, multiple times daily). The device is used only by licensed healthcare professionals who monitor patient response, and the user manual includes explicit warnings about monitoring skin during cold therapy. A 120-minute maximum does not introduce new safety concerns.
Compression-Only Treatment Time	Adjustable: 0 to 120 minutes. Default: 30 minutes.	5 to 60 minutes. Default: 15 minutes.	The longer maximum treatment time for compression is consistent with established clinical practice for post-surgical compression. The device is intended for use under healthcare professional supervision. No new safety concerns.
Heat Therapy Treatment Time	Not applicable — no heat therapy function.	5 to 30 minutes. Default: 15 minutes.	Not applicable to Cryo Sport 2.0, which does not include heat therapy.
Contrast Therapy Treatment Time	Not applicable — no contrast therapy function.	Total 15–90 minutes (default 30 min); Heat cycle: 1–10 min; Cold cycle: 1–10 min.	Not applicable to Cryo Sport 2.0, which does not include contrast therapy.
Timer Resolution / Default	5-minute resolution. Default: 30 minutes.	Varies by modality (5-minute increments). Default: 15 minutes.	Both devices use incrementally adjustable timers. The Cryo Sport's default of 30 minutes aligns with clinical recommendations for cold therapy. No safety concern.

9. Operating and Storage Conditions			
Operating Temperature	0°C to 40°C (32°F to 104°F).	50°F to 90°F (10°C to 32°C).	The Cryo Sport 2.0 operates across a wider range (0–40°C) than the predicate (10–32°C). Both are adequate for indoor professional clinical use. No safety concern.
Storage Temperature	1°C to 50°C.	33°F to 122°F (1°C to 50°C).	Identical — substantially equivalent.
Relative Humidity	Operating: 30–90% non-condensing. Storage: 30–90% non-condensing.	Operating: 30–90% non-condensing. Storage: 10–95% non-condensing.	Operating humidity ranges are identical. Storage range of Cryo Sport is slightly narrower than predicate; both are adequate for standard healthcare storage environments. No safety concern.
Atmospheric Pressure	80 kPa to 102 kPa (transport/storage).	0–9,842 ft (0–3,000 m) altitude equivalent.	Equivalent operating ranges suitable for standard healthcare facility environments. Substantially equivalent.
10. Accessories / Patient-Contacting Components			
Wraps / Garments	One wrap included; various wrap types available for different anatomical areas. Applied to intact skin or over dressing.	Various anatomical wraps: knee (straight/articulated), elbow (standard/flexed), ankle, shoulder, back, hip-groin, hand-wrist, half-leg boot. Applied to intact skin or over sterile dressings.	Both devices use flexible garments/wraps to deliver cold and compression therapy. Patient-contacting materials must demonstrate biocompatibility per ISO 10993-1. Both are provided non-sterile and applied over intact skin or dressings. Substantially equivalent approach.
Sterility	Non-sterile. Not intended to be user-sterilized. Applied over intact skin or dressings.	Non-sterile. Not intended to be user-sterilized. Applied over intact skin or sterile dressings.	Identical approach — substantially equivalent.
Biocompatibility of Patient-Contacting Parts	Evaluated per ISO 10993-1. Surface contact with intact skin (limited/prolonged duration). Cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10), and other applicable tests performed.	ISO 10993-1, -5, -10, -12. Wraps and connector hose exteriors tested — found biocompatible for skin contact.	Both devices follow the same biocompatibility evaluation framework for patient-contacting components. Substantially equivalent.

None of the performance or technological differences identified between the Cryo Sport 2.0 and the predicate Med4 Elite™ raise any new questions of safety or effectiveness. Each difference has been reviewed in the context of the device's intended use, design, applicable standards, and existing predicate data.

Non-Clinical and/or Clinical Tests Summary & Conclusions *21 CFR 807.92(b)*

The Cryo Sport 2.0 (AVA501) has been subjected to a comprehensive program of design verification and validation testing covering electrical safety, electromagnetic compatibility (EMC), software validation, system/bench performance testing, biocompatibility, and environmental/transport testing. The results confirm that the device is safe and effective for its intended use and is substantially equivalent to the predicate device.

A. Electrical Safety Testing

Tested for compliance with IEC 60601-1 (3rd edition) and applicable national deviations. Testing included:

- Dielectric strength (hipot) testing of mains insulation
- Leakage current measurements (earth leakage, enclosure leakage, patient auxiliary current)
- Protective earth resistance verification
- Temperature rise testing under normal and single-fault conditions
- Battery safety testing per IEC 60601-1 Clause 14

Result: All electrical safety tests passed. The device meets IEC 60601-1 requirements for Class II, Type B applied part equipment.

B. Electromagnetic Compatibility (EMC)

EMC testing conducted per IEC 60601-1-2 (4th edition). Tests included radiated/conducted emissions (CISPR 11), ESD immunity (IEC 61000-4-2), radiated RF immunity (IEC 61000-4-3), EFT/burst (IEC 61000-4-4), surge (IEC 61000-4-5), conducted RF immunity (IEC 61000-4-6), magnetic field immunity (IEC 61000-4-8), and voltage dips/interruptions (IEC 61000-4-11).

Result: The device met all applicable emissions limits and demonstrated acceptable performance under all immunity tests.

C. Software Verification and Validation (V&V)

Firmware AVA501 V.1.0.0 classified as Moderate Level of Concern per FDA guidance. Documentation included software requirements specification (SRS), software design specification (SDS), unit/integration/system testing, hazard analysis (ISO 14971), boundary and stress testing of all therapy control algorithms, and alarm/fault condition verification.

Result: All software V&V activities passed.

D. System and Bench Performance Testing

- Compression accuracy: Pressure delivery verified at all preset levels (0, 25, 50, 75 mmHg continuous; intermittent modes). Measured values within ±25% of set value as specified.
- Water flow rate: Flow measured at Low, Medium, and High settings. Values confirmed within ±25% of nominal (53, 56, 64 L/h respectively).
- Temperature thermometer accuracy: Confirmed at ±2°C across the 1°C–40°C operating range.
- Battery runtime: Approximately 4 hours of continuous operation on full charge confirmed.
- Timer accuracy: Confirmed ±30 seconds accuracy across the 5–120 minute operating range.
- Reservoir integrity: No leakage observed under fill-line conditions during extended operation.

Result: All system performance parameters met specification.

E. Biocompatibility

Patient-contacting components (wrap/heat exchanger sleeve) evaluated per ISO 10993-1 for surface contact with intact skin (limited/prolonged duration). Testing performed:

- Cytotoxicity (ISO 10993-5): Pass
- Sensitization (ISO 10993-10, Guinea Pig Maximization Test): Pass
- Irritation / skin irritation (ISO 10993-10): Pass
- Test sample preparation per ISO 10993-12

Result: All patient-contacting components demonstrated biocompatibility for the intended contact type and duration.

F. Cleaning and Disinfection Validation

Cleaning and disinfection procedures validated for compatibility with specified cleaning agents over the expected device service life (5 years). Wraps confirmed to tolerate repeated cleaning with mild detergent/antibacterial soap and cold water without degradation of materials or performance.

Result: Cleaning and disinfection procedures are adequate and validated.

G. Environmental and Transport Testing

Device tested under environmental stress conditions consistent with specified storage and operating conditions per IEC 60068 (temperature cycling, humidity exposure, transport/vibration simulation). The device performed within specification following all environmental tests.

H. Risk Management

A comprehensive risk management process was conducted per ISO 14971. All identified hazards were analyzed, and residual risks were determined to be acceptable in the context of the intended clinical benefit. No residual risks requiring special labeling beyond those already included in the Instructions for Use were identified.

Conclusion of Substantial Equivalence *21 CFR 807.92*

Based on the information provided in this 510(k) Summary, Avanutri Equipamentos de Saude concludes that the Cryo Sport 2.0 (AVA501) is substantially equivalent to the predicate device Med4 Elite™ (K171685, CoolSystems, Inc. dba Game Ready) with respect to both indications for use and technological characteristics, in accordance with Section 513(i) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 807.92.

- The Cryo Sport 2.0 has the same intended use as the predicate: treatment of post-surgical and acute injuries to reduce edema, swelling, and pain through cold and compression therapy, for use by licensed healthcare professionals in professional clinical settings.
- The technological differences identified (ice-based cooling, portable/battery-powered design, compact form factor, single-patient use, cold-and-compression-only modalities) do not raise new questions of safety or effectiveness.
- The device has been subjected to comprehensive non-clinical testing (electrical safety, EMC, software V&V, bench performance, biocompatibility, environmental) with all tests passing applicable requirements.
- All patient-contacting components have been demonstrated to be biocompatible for the intended contact type and duration.
- The device complies with IEC 60601-1 (Class II, Type B), IEC 60601-1-2, ISO 10993-1, ISO 13485, and ISO 14971.

The Cryo Sport 2.0 (AVA501) is safe and effective for its intended use and is substantially equivalent to the legally marketed predicate device.