K072620

510(k) Summary of Safety and Effectiveness

Game Ready Classic System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

OCT 31 2007

A. Submitter:

CoolSystems, Inc.
2201 Dwight Way
Berkeley, CA 94704

Phone: 510-868-5378
Fax: 510-984-5330
Email: mbaldwin@gameready.com
Contact: Marianne Baldwin, VP, QA/RA/CA

Date Prepared: September 14th, 2007

B. Device Names:

Trade Name: Game Ready Classic System
Common/usual Name: Cold/compression therapy system
Classification Name: Powered inflatable tube massager /Cold water circulating pack

C. Predicate Device:

The Game Ready Classic System is substantially equivalent to the Game Ready System, cleared under 510(k) K071050, and currently legally marketed by CoolSystems, Inc.

D. Device Description:

The Game Ready Classic System is comprised of the following components:

- Control Unit, with AC Adapter (to convert line power to DC input power)
- Connector Hose (connects Control Unit to Wrap)
- Wrap (Heat Exchanger + Sleeve)
- Optional Carry Bag
- Optional Battery Pack (under development)

The Game Ready Classic System is a DC-powered device that provides intermittent compression and controlled cold therapy by controlling fluid flow and air pressure through a Wrap that is specially designed for a specific body part or location (e.g., shoulder, elbow, knee, ankle, back). A Wrap is comprised of a Sleeve (the outer covering for the Heat Exchanger) and a Heat Exchanger. Cooling is provided by

circulating ice water from the Control Unit through the Connector Hose to the Wrap. Compression is provided by an intermittent-cycling pneumatic pump that pumps air from the Control Unit through the Connector Hose to the Wrap. The user can adjust the amount of compression, the amount of cooling, and the treatment time. The Control Unit software is designed to protect both the user and the Control Unit from harm by shutting off the system and sounding an alarm if there is insufficient fluid flow or in case of an over-pressure or under-pressure situation. The software detects other, less-serious error conditions and sounds a warning beep to alert the user, so that the error condition can be corrected. These protections have been carried forward from the original Game Ready to Game Ready Classic.

E. Intended Use:

The Game Ready Classic 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.

F. Comparison with the Predicate Device:

The Game Ready System Classic System is substantially equivalent to the predicate device in design, function, and indications for use/intended use.

G. Non-Clinical Testing

Bench testing was performed at the component and system level. The testing showed that the Game Ready Classic System met its requirements. Design Verification Testing showed that the Game Ready Classic System performed according to specification.

H. Clinical Testing

No clinical testing data are submitted, referenced, or relied on to determine substantial equivalence.

I. Conclusions

There are no significant differences between the Game Ready Classic System and the predicate device that would adversely affect the use of the proposed device or introduce new potential risks or safety concerns. The Game Ready Classic System is substantially equivalent to the predicate device in design, function, and indications for use/intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2007

CoolSystems, Inc
% Ms. Marianne Baldwin
2201 Dwight Way
Berkeley, CA 94704

Re: K072620
Trade/Device Name: Game Ready Classic System 550550
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: II
Product Code: IRP, ILO
Dated: September 14, 2007
Received: September 17, 2007

Dear Ms. Baldwin:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Peter Rumm
Dep D. Director
10/3/07

Mark Melkerson
Director
Division of General Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Game Ready™ Classic System

Indications for Use:

The Game Ready Classic 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.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072620