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K033720

510(k) Summary

Pursuant to the requirements of 21 CFR 807.92, this 510(k) summary of safety and effectiveness is provided.

1. Sponsor Information:

   ARI
   2523 South McDonough Road
   Orchard Hill, Georgia 30266

   Contact:
   Gordon Dixon
   President
   Phone: 770-227-8222
   Fax: 770-227-9190

   Establishment Registration Number: 1037559

2. Device Identification

Device Trade Name	ARI Cold Spray
Common Name:	Cold Spray, Vapocoolant
Device Classification Name:	Vapocoolant
Classification:	Unclassified
Device Product Code:	MLY
Special Controls:	None

3. Predicate Device

   K021726 Gebauer's Instant Ice™ (Mist Spray and Stream Spray
   Sold as a non-prescription over-the-counter product.

4. Description

   ARI Cold Spray is designed to deliver propane, isobutane, n-butane in a spray. The mixture is self-propelled from the container due to the high vapor pressure of the contents.

   The form of delivery is appropriate when the consumer follows the labeled directions for use. The cooling action is provided through rapid evaporation of the non-medicated propellants.

5. Intended Use of Device

Cold Spray is intended to be used as a topical skin refrigerant to be used like ice for the temporary relief and reduction of minor pain and swelling from sprains, bruising, contusions and minor sports injuries.

6. Technical Summary

Cooling effects of both devices (predicate and ARI Cold Spray), act in the same manner. The cooling effect experienced by the patient is caused by the evaporation of the chemical mixture on the skin. A chemical mixture is contained within a can, filled under pressure and dispensed using standard aerosol nozzle technology. The consumer applies the contents by pressing on a nozzle to dispense the product, onto the skin.

7. Determination of Substantial Equivalence

There is demonstrated equivalency in basic product design, technology, and indications for use, risk factors and target populations.

While the chemical compositions are different, the temperature characteristics are similar in that both have measurable cooling effects on the skin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 10 2005

ARI, Inc.
C/o Ms. Cathryn N. Cambria
5536 Trowbridge Drive
Dunwoody, Georgia 30338

Re: K033720
Trade Name: ARI Cold Spray
Regulatory Class: Unclassified
Product Code: MLY
Dated: March 29, 2005
Received: April 1, 2005

Dear Mr. Borsai:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OTC Indications for Use

510(k) Number (if known): K033720

Device Name: ARI Cold Spray

Indications for Use:
The ARI Cold Spray is intended to be used as a topical skin refrigerant to be used like ice for the temporary relief and reduction of minor pain and swelling from sprains, bruising, contusions and minor sports injuries.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K033720