April 19, 2018

ITW Contamination Control Electronics
Steve Cook
Director of Product Technology
8125 Cobb Center Drive
Kennesaw, Georgia 30152

Re: K172598
Trade/Device Name: Coventry™ Topical Anesthetic Mist Spray HAZMAT FREE, Coventry™ Topical Anesthetic Stream Spray HAZMAT FREE
Regulatory Class: Unclassified
Product Code: MLY
Dated: January 29, 2018
Received: January 29, 2018

Dear Steve Cook:

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. 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); 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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172598

Device Name
Coventry ™ Topical Anesthetic Mist/Stream Spray HAZMAT FREE

Indications for Use *(Describe)*
Coventry ™ Mist Spray and Medium Stream Spray are vapocoolants (skin refrigerants) intended for topical application to skin, intact mucous membranes (oral cavity, nasal passage ways and the lips) and minor open wounds. Coventry ™ controls pain associated with injections (venipuncture, IV starts, cosmetic procedures), minor surgical procedures (such as lancing boils, incisions, drainage of small abscesses and sutures) and the temporary relief of minor sports injuries (sprains, bruising, cuts and abrasions). Coventry ™ Medium Stream Spray is also intended for use the management of myofascial pain, restricted motion and muscle tension.

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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ITW Contamination Control Electronics

510(k) Summary

Coventry ™ Topical Anesthetic Spray

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92(c).

I. SUBMITTER

Owner:
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(770) 424 4888

Contact Person:
Steve Cook
ITW CCE
3125 Cobb Center Drive
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(770) 424-4888

Date Prepared:
August 25, 2017

II. DEVICE

Trade Name:
Coventry ™ Topical Anesthetic Spray
Part number - 700-453, 700-454

Common Name:
Cold Spray - 245fa (1,1,1,3,3-Pentafluoropropane) and 134a (1,1,1,2-Tetrafluoroethane)

Classification Name:
Refrigerant Topical, Vapocoolant

Product Code:
MLY

III. PREDICATE DEVICE

Primary:
Gebauer's Pain Ease (Medium Stream Spray & Mist Spray)
Gebauer Company.
K032671
Legally marketed medical device

IV. DEVICE DESCRIPTION

The predicate is a legally marketed device.

Coventry™ Topical Anesthetic Spray HAZMAT FREE (subject device) is a non prescription device designed to deliver a standard mixture 245fa (1,1,1,3,3-Pentafluoropropane) and 134a (1,1,1,2-Tetrafluoroethane), which is being offered in two delivery configurations, Mist Spray Model No. 700-453 and Medium Stream Spray Model Number 700-454 This mixture self-propels itself from the delivery system, which is designed to account for its low vapor pressure. The device's delivery system controls the amount of the Coventry ™ mixture that is dispensed, the Mist Spray configuration produces very fine droplets that create cooling at the points of contact. The Medium Stream Spray configuration produces a pinpoint stream that contacts the skin surface at a specific single location. Both configurations contain the same standard mixture thus there is not safety or effectiveness concerns between configuration. The skin is cooled through rapid evaporation of the non-medicated propellants.

Coventry ™, is substantially equivalent, if not identical, to the predicate device Gebauer's Pain Ease (Mist Spray and Medium Stream Spray). Both devices are indicated for use to control pain for pre-injection anesthesia, minor procedures, and minor sports injuries.

The distance and amount applied is determined by the user.

V. INDICATIONS FOR USE

The Indications for Use is similar to the predicate device.

Coventry ™ Mist Spray and Medium Stream Spray are vapocoolants (skin refrigerants) intended for topical application to skin, intact mucous membranes (oral cavity, nasal passage ways and the lips) and minor open wounds. Coventry ™ controls pain associated with injections (venipuncture, IV starts, cosmetic procedures), minor surgical procedures (such as lancing boils, incisions, drainage of small abscesses and sutures) and the temporary relief of minor sports injuries (sprains, bruising, cuts and abrasions). Coventry ™ Medium Stream Spray is also intended for use the management of myofascial pain, restricted motion and muscle tension.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device has the same technical characteristics as the predicate device including materials, design, and energy source. There are no technological differences between the predicate and the submitted device. Refer to the following table for the comparison between the subject device and the predicate:

Comparison Chart – Technological Characteristics		
Trade Name	Gebauer's Pain Ease *Predicate*	*Coventry ™ Topical Anesthetic Spray subject device*
Product Design	Pressurized dispensing container, which includes the vapocoolant, canister, valve, actuator, and cap	Pressurized dispensing container, which includes the vapocoolant, canister, valve, actuator, and cap
Indication for Use and Intended Use	Gebauer's Pain Ease Mist Spray and Medium Stream Spray are vapocoolants (skin refrigerant) intended for topical application to skin, intact mucous, and minor open wounds. Pain Ease controls pain associated with injections (venipuncture, IV starts, cosmetic procedures), minor surgical procedures (such as lancing boils, incisions, drainage of small abscesses, and sutures), and the temporary relief of minor sports injuries (sprains, bruising, cuts and abrasions). Pain Ease Medium Stream Spray is also intended for the treatment of myofascial pain caused by trigger points, restricted motion and muscle tension.	Coventry ™ Topical Anesthetic Spray Medium Stream and Mist Sprays are vapocoolants (skin refrigerants) intended for topical application to skin, intact mucous membranes (oral cavity, nasal passage ways and the lips) and minor open wounds. Coventry ™ controls pain associated with injections (venipuncture, IV starts, cosmetic procedures), minor surgical procedures (such as lancing boils, incisions, drainage of small abscesses and sutures) and the temporary relief of minor sports injuries (sprains, bruising, cuts and abrasions). Coventry ™ Medium Stream Spray is also intended for use the management of myofascial pain, restricted motion, muscle tension
Product Fill Volume	3.5oz (103.5mL)	3.5oz (103.5mL)
Vapocoolant Composition	1,1,1,3,3-Pentafluoropropane (HFC-245fa) 95% and 1,1,1,2-Tetrafluoroethane (HFC-134a) 5%	1,1,1,3,3-Pentafluoropropane (HFC-245fa) 95% and 1,1,1,2-Tetrafluoroethane (HFC-134a) 5%
Energy delivered	Thermal Energy via Refrigerant Spray	Thermal Energy via Refrigerant Spray
Energy Deposited	N/A	N/A
Vapocoolant Discharge Method	Depress the Actuator Button to release the vapocoolant	Depress the Actuator Button to release the vapocoolant
Environmental Compatibility	Non-Flammable	Non-Flammable
Mechanical Safety	Mechanism has positive shut-off release	Mechanism has positive shut-off release

Substantial Equivalence:

The predicate device is a legally marketed device. The subject device has similar intended use (Indications for Use) as the predicate device. 21 CFR 807.107(b)(1)

The subject device has the same technological characteristics as the predicate device. There are no technological differences, including no changes in the materials, design, energy source, or other features of the device from those of the predicate device. 21 CFR 800.107(b)(2)(i)

The subject device and the predicate device use an identical (substantially equivalent) chemical composition by type and percent of components: 245fa (1,1,1,3,3-Pentafluoropropane) at 95% of the total and 134a (1,1,1,2-Tetrafluoroethane) at 5% of the total mixture.

The subject device and the predicate device use the same materials, design, energy source and other features.

The subject device is a reverse-engineering of its predicate.

Differences, if any, would be limited to discussion and promotion of product, marketing materials, cosmetic labeling, only.

The subject device does not raise questions of safety and effectiveness efficacy different from the predicate device.

Labeling:

The labeling of subject device has been prepared to ensure the medical professional has adequate and clear instructions for safety and usage. The canister labeling, directions for use, safety and warning statements are substantially equivalent to the predicate.

Summary: Coventry ™ is substantially equivalent and no technological differences exist to the predicate device. 21 CFR 800.107(b)(2)(i)

VII. PERFORMANCE DATA

The predicate and the subject devices use the same materials, design and energy source and no technological differences exist. Tests were selected and performed to ensure the subject device's output performance are the same as its predicate. The following tests were performed in support of substantial equivalence:

Chemical Composition Confirmation

Both systems use identical aerosols profiles: 245fa (1,1,1,3,3-Pentafluoropropane) at 95% of the total and 134a (1,1,1,2-Tetrafluoroethane) at 5% of the total mixture.

The subject device's aerosol is checked and verified upon receipt from the aerosol supplier to ensure the same chemical profile as the predicate.

Biocompatibility

The submission included evidence supporting the biocompatibility of the device

Structural and Parts Composition

Engineering verification measurements were taken and visual inspections were made to determine the canisters, valves, and caps were substantially equivalent between the predicate and the subject device.

Directions for Use Application and Methodology:

All key elements of the Directions for Use (DFU) for the predicate device and the subject device are all substantially equivalent including indication for use, intended use, precaution statements, warning statements, and contraindication statements, and treatment regiment. No substantial differences exist between the predicate and subject device's Directions for Use.

Stability Protocol and Shelf Life Testing

A stability protocol was developed to ensure that the identity, strength, quality, and purity of the product is maintained throughout its labeled dating period. Testing assessments were conducted under controlled conditions at room temperature and under accelerated conditions. All requirements were confirmed to meet established acceptance criteria.

Summary

Based on the testing performance conducted the subject device, Coventry ™ was found to have a safety and effectiveness profile that is similar, if not identical, to the predicate device, Gebauer's Pain Ease.

VIII. CONCLUSION

Based on the information presented above and within this submission, it is concluded that the Coventry ™ is safe and effective for its intended use and is substantially equivalent to the predicated device. Also, the labeling is substantially equivalent to the predicate device.