DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 26, 2016

Riemser Pharma
% Kenneth Kleinhenz
Owner, Quality Systems Resources (qsr)
10807 Dakota Ranch Rd.
Santee, California 92071

Re: K160943
Trade/Device Name: Bite Away
Regulation Number: 21 CFR 890.5740
Regulation Name: Powered Heating Pad
Regulatory Class: Class II
Product Code: IRT
Dated: July 25, 2016
Received: July 28, 2016

Dear Mr. Kleinhenz:

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.

We note that your device exceeded the Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 CFR Part 890.9), and therefore required the submission and clearance of a premarket notification prior to commercial distribution in the United States.

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 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -A

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)*
K160943

Device Name
Bite Away

Indications for Use *(Describe)*
The Bite Away is indicated for use to provide temporary relief of the pain and itching resulting from insect stings and bites such as bees, wasps and mosquitoes by temporarily increasing localized blood flow.

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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DATE OF PREPARATION August 25, 2016

ADMINISTRATIVE INFORMATION

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Regulatory Affairs
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DEVICE NAME

Classification Name: Infrared Lamp

Trade/Proprietary Name: Bite Away

ESTABLISHMENT REGISTRATION NUMBER
3007770022

DEVICE CLASSIFICATION AND PRODUCT CODE
As shown in 21CFR 890.5740 (powered heating pad), a powered heating pad is an electrical device intended for medical purposes that provides dry heat therapy for body surfaces. It is capable of maintaining an elevated temperature during use. These devices are classified as Class II. Powered heating pads have been assigned Product Code IRT.

INTENDED USE
The Bite Away is indicated for use to provide temporary relief of the pain and itching resulting from insect stings and bites such as bees, wasps and mosquitoes by temporarily increasing localized blood flow.

DEVICE DESCRIPTION

Design Characteristics

The Riemser Pharma Bite Away device is a light weight, portable, hand held, battery powered, user-operated device that produces mild heat for direct contact with the affected areas of the skin. The heat is initiated by the user through the activation of the unit by depressing a non-locking button. The device is provided with two (2) side-by-side buttons. The user has the choice of a short 3 second heat treatment or a 6 second heat treatment depending on which button is depressed. The activation of the unit is signified with the illumination of an LED light and an audible chirp through the use of an electronic buzzer. An audible alarm is activated when there is a user error. The device is not connected to the user as the user is in complete control of the heat treatment and as such, self-delivers the heat treatment to themselves by contacting the device to their own anatomy / treatment site. The short duration of 3 and 6 seconds of heating the device's heated ceramic plate that contacts the patient further alleviates risk of overheating the skin as the device automatically stops heating the element after 3 or 6 seconds; limiting the maximum amount of heat to be delivered to the site.

The Riemser Pharma Bite Away device utilizes two AA batteries (1.5 volts each) that power a resistor that heats a 9mm ceramic disc to 51.5°C +/- 1% when activated by the user through the use of one of the two electro-mechanical NOC (normal open contact) buttons (3 seconds or 6 seconds of heating). The device consists of a few major components: a hard plastic outer case, a printed circuit board, an activation button, AA batteries, and a heated ceramic plate that contacts the patient. The printed circuit board consists of the following components: electro-mechanical NOC buttons, microcontroller with programmed firmware, MOSFET transistor heating element, ceramic pad, resistors, coils, capacitor, thermistor temperature sensor and buzzer.

The Riemser Pharma Bite Away device is approximately 6 inches long and weighs approximately 25 grams. The Bite Away device is provided in 2 shapes, both of which are identical in every way except for the shape. One product is an elongated configuration called "Cobra" and the other configuration is an oblong configuration called "Mouse". Although these products have different shapes and names, the products are identical in every way to include raw materials, subcomponents, electronic circuits, electronic components, and imbedded software code, fabrication processes, etc., and only differs in the shape of the outer case (elongated Cobra model versus the oblong Mouse model).

Non-Clinical Testing:

The Riemser Pharma Bite Away device demonstrated compliance with the appropriate sections of the following electrical standards: IEC 60601-1 (MOD), IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11 and IEC 62366. The patient contact polymers and ceramics were tested against the ISO 10993 standards (Biological Evaluation of Medical Devices) such as: ISO 10993-5 and ISO 10993-10.

Clinical Testing

The Riemser Pharma Bite Away device was evaluated in a prospective, single arm, open label clinical study for the temporary relief of the pain and itching resulting from insect stings and bites such as bees, wasps and mosquitoes in 146 subjects. A total of 93 patients (64%) received a sting from a wasp, 33 patients (23%) receive a bite from a mosquito, and 8 patients (5%) received a sting from a bee. Among all patients, 108 subjects (74%) had swelling, 85 subjects (58%) had pain, 84 (57%) had erythema, 52 subjects (36%) had pruritus, and 2 had dyspnea. A visual analog scale (VAS) for pain and swelling was utilized to assess the effectiveness of the Bite Away device, with a score of 10 being the worst pain/swelling and zero (0) being no pain or swelling. The VAS score for swelling decreased with statistical significance after the use of the Bite Away device to treat the insect bite / sting. Bite Away treatment reduced swelling VAS scores from a mean of 4 prior to treatment, to a mean VAS score of 2 after 2-5 minutes post treatment and a VAS score of 1 after 10 minutes post treatment ($p < 0.0001$). The same trend was observed with the VAS pain scale. A mean VAS pain score of 6 was observed prior to Bite Away treatment compared to a mean VAS score of 2 after 2 minutes post treatment, a mean VAS score of 1 after 5 minutes post treatment, and a mean VAS score of 0 after 10 minutes post treatment ($p < 0.0001$). Similar trends were also observed with pruritus scores as the mean VAS score was 5 prior to Bite Away treatment compared to mean VAS scores of 2 after 2 minutes post treatment and mean VAS scores of 0 after 5 and 10 minutes post treatment ($p < 0.0001$).

EQUIVALENCE TO MARKETED PRODUCT

The Riemser Pharma Bite Away device shares a similar intended use and design principles with the following primary predicate device Hontech Li's Itch Stopper (K963824), which have been determined by FDA to be substantially equivalent to the Bite Away device. The Jenex Therapik (K964397) was used as a reference device based on the ability of Therapik and the Bite Away device to deliver heat therapy for temporary relief of the pain and itching resulting from insect stings and bites from bees, wasps and mosquitoes.

Indications For Use

The Riemser Pharma Bite Away device shares similar intended use with the predicate device and the reference device as all devices are indicated for temporary relief of insect bites and stings. The Bite Away device has an expanded indication for use as compared to the primary predicate. Specifically, the Bite Away device is intended to provide temporary relief from pain and itching from wasps, bees, and mosquitos based on a temporary increase in blood flow. While the Hontech Li's Itch Stopper (K963824) is intended for mosquito bites. Clinical data was used to support the expanded indications for use. Furthermore, the reference device Riemser Pharma Bite Away device shares identical indications for use language with the Jenex Therapik, (K964397) device and is based on similar technological characteristic of heat delivery for temporary relief of pain and itching from wasps, bees, and mosquitos.

Design and Materials

The design principles of the Riemser Pharma Bite Away and the primary predicate device [Hontech Li's Itch Stopper (K963824)] and the reference device [Jenex Therapik (K964397)] are substantially equivalent as they all share common design principals of being user-operated, hand-held, light weight, battery powered, reusable devices that deliver mild heat to the skin/dermis as a means to transfer heat from the device to the user-directed anatomical location. All devices share the common design feature of user-applied heat therapy that is directed and controlled solely by the user. All devices also share the common design feature of being loosely packaged in a paperboard box. The Riemser Pharma Bite Away and the Jenex Therapik (K964397) device share the design feature of being over-the-counter (OTC) devices under 21 CFR 890.5500 while the Hontech Li's Itch Stopper (K963824) is 510(k) exempt under 21 CFR 890.5740.

The materials of the Riemser Pharma Bite Away and the primary predicate and reference device are substantially equivalent as they all utilize a plastic polymer outer shell to house the electrical components of the device. Riemser Pharma Bite Away , the Jenex Therapik (K964397) and Hontech Li's Itch Stopper (K963824) also share material characteristics of utilizing an alkaline battery to power the device along with sharing the same material characteristics of utilizing an electronic circuit board.

The Riemser Pharma Bite Away, the Jenex Therapik (K964397), and the Hontech Li's Itch Stopper (K963824) all deliver heat to the skin/dermis. The Hontech Li's Itch Stopper (K963824) utilizes a heated disc of 58°C, the Jenex Therapik (K964397) heated bulb delivers 50°C – 60°C, and the Riemser Pharma Bite Away delivers 50°C - 53°C.

The Riemser Pharma Bite Away, the Jenex Therapik (K964397), and the Hontech Li's Itch Stopper (K963824) all utilize low voltage batteries (3 - 9 Volts) to power the hand-held units. All devices focus the energy to a focal point on the device (bulb or metallic / ceramic disc) as a means to deliver focused heat energy to a localized area of the skin.

The Riemser Pharma Bite Away, the Jenex Therapik (K964397), and the Hontech Li's Itch Stopper (K963824) have a controlled time of heat delivery that ranges from a few seconds to a few minutes. The Riemser Pharma Bite Away has a time of heat delivery of 3 to 6 seconds while the Jenex Therapik (K964397) device has a time of heat delivery of 20 – 30 seconds.

The Riemser Pharma Bite Away device shares design, material and indications for use characteristics with the following predicate and reference devices as outlined in the table below:

	Subject Device	Primary Predicate	Reference Device
	Riemser Pharma Bite Away	Hontech Foundation for Medical Technology Li's Itch Stopper (K963824)	Jenex, Corp. (Thermolabile Technologies, Corp) Therapik (K964397)
Intended Use	Delivery of mild heat to the skin/dermis	Delivery of mild heat to the skin/dermis	Delivery of mild heat to the skin/dermis
Indications for Use	The Bite Away is indicated for use to provide temporary relief of the pain and itching resulting from insect stings and bites such as bees, wasps and mosquitoes by temporarily increasing localized blood flow.	For prompt temporary stopping for up to 24 hours of skin itching due to insect (mosquito) bites.	The Therapik is indicated for use to provide temporary relief of the pain and itching resulting from insect stings and bites such as bees, wasps and mosquitoes by increasing localized blood flow.
Design	Hand held device that heats a metallic disc with a resistor to temperatures of 51.5°C	Hand held device that heats a metallic disc with a resistor to temperatures of 58°C	Hand held device that heats a metallic disc with a resistor to temperatures of 50°- 60°C
Range of Temperatures	50 - 53°C	58°C	50°- 60°C
Operator Directed/Applied to the Skin	Yes	Yes	Yes
Weight	25 grams	70 grams	39 grams
Duration of Use	3 and 6 seconds	Approximately 20 seconds	20-30 seconds
Dimension of Heated Area on the Device	9 mm	26 mm	11 mm
Power Source	AA Batteries	AA Batteries	9 V Battery
Voltage	3 volts DC	3 volts DC	9 volts DC
Energy Source	Heated ceramic disc	Heated metallic disc (nickel coated steel)	Heated bulb
Hard Plastic Outer Case	Yes	Yes	Yes
LED Light	Yes	Yes	No
Audible Alarm	Yes	No	No
Metallic Disc to Deliver Heat to Skin	Yes	Yes	No
Microprocessor	Yes	Yes	No
Classification Name	Infrared Lamp	Powered Heating Pad	Infrared Lamp
OTC Use	Yes	Yes	Yes
Product Code	2	2 - Exempt	2
Product Code	ILY	IRT	ILY
CFR Section	890.5500	890.5740	890.5500