June 23, 2022

MibeTec, GmbH
% Kenneth Kleinhenz
Official Correspondent
QSR Consulting
10807 Dakota Ranch Road
Santee, California 92071

Re: K220514
Trade/Device Name: bite away® neo
Regulation Number: 21 CFR 890.5740
Regulation Name: Powered heating pad
Regulatory Class: Class II
Product Code: IRT
Dated: March 30, 2022
Received: April 1, 2022

Dear Kenneth 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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

For Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220514

Device Name
bite away® neo

Indications for Use *(Describe)*
The bite away® neo 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.

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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Date Prepared: 21 June 2022

I. SUBMITTER

Manufacturer Name:

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Munchener Strasse 15
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D-17493
+49 34954 247 489 telephone

Mfg. Establishment Registration Number: 3015733772

Official Contact: Kenneth K. Kleinhenz
Regulatory Affairs
Telephone (619) 244-9573
Kleinhenz64@gmail.com

II. DEVICE

Name of Device:	bite away® neo
Common or Usual	Heating pad
Name: Classification	Powered Heating Pad (21 CFR 890.5740)
Name Regulatory Class:	II
Product Code:	IRT
510(K) Identification:	K220514

III. PREDICATE DEVICE

Riemser Bite Away, K160943

IV. DEVICE DESCRIPTION

Design Characteristics

The bite away® neo 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 5 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 5 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 5 seconds; limiting the maximum amount of heat to be delivered to the site.

The bite away® neo device utilizes two AA batteries (1.5 volts each) that power a resistor that heats a 7mm ceramic disc to approximately 50°C when activated by the user through the use of one of the two electro-mechanical NOC (normal open contact) buttons (3 seconds or 5 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 bite away® neo device is approximately 7 inches long and weighs approximately 40 grams.

Material Composition

The bite away® neo device housing is fabricated with biocompatible polymers and the heated disc is fabricated with a biocompatible ceramic material. The electronics are fabricated on a standard electrical circuit board with standard electronics (capacitors, resistor, microprocessors, etc.).

V. INDICATIONS FOR USE

The bite away® neo 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.

INTENDED USE

Delivery of mild heat to the skin / dermis

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The bite away® neo Device shares indications for use and design principles with the following predicate device: bite away (Riemser, K160943); a Class II medical device that was cleared for marketing in the United States under K160943**.**

Indications For Use

The bite away® neo Device and the bite away (Riemser, K160943) predicate device are substantially equivalent with respect to their indications for use as they are both indicated for the same intended use of temporary relief from the pain and itching resulting from insect stings and bites. Additionally, the bite away® neo and the bite away predicate device shares indications for use principles of being OTC (over the counter).

Design and Materials

The design principles of the bite away® neo and the bite away predicate device (K160943) are substantially equivalent as they all share common design principals of being a 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. The bite away® neo and the bite away predicate device (K160943) share a common material and design principal of utilizing a ceramic disc to transfer the heat from the device to the skin. The bite away® neo and the bite away predicate device also share common design and material features of utilizing a light-weight polymer outer case to hold and contain the electronics and AA batteries that power the device. Both devices also share the common design feature of being form-fit packaged in a paperboard box. The bite away® neo and the bite away predicate device (K160943) share the design feature of being over-the-counter (OTC) devices under 21 CFR 890.5740. The delivery of heat to the insect bite is delivered and controlled by the user. Device weight does not play a role in the delivery of heat. A weight difference of 15 grams is virtually indistinguishable by the user. Therefore, differences in device weight do not affect safety or efficacy. Differences in contact time by 1 second (5 sec. versus 6 sec) do not affect safety or efficacy and only plays a role in greater safety as it creates a larger margin of safety against burns to the skin. The reduced heat contact time of 1 second does not affect efficacy given the fact that the user can reapply the heat with an additional heat treatment if necessary. The subject device and the predicate device have the same indications for use with respect to insect bites and only differ in the claimed mechanism of action (blood flow), which has no affect on safety or efficacy because the mechanisms of action does not affect the subjects use of the device.

The bite away® neo device is substantially equivalent to the bite away predicate device (K160943) in the following respects:

	Subject Device	**Predicate Device** (K160943)	**Rationale for no Effect on Safety and Efficacy**
	bite away® neo	**bite away**	
Manufacturer	**mibeTec, GmbH**	**Riemser Pharma**	**Validated Process**
Device Name	**bite away® neo**	**bite away**	Device name does not imply any claims. No additional risks
Intended Use	Delivery of mild heat to the skin/dermis	Delivery of mild heat to the skin/dermis	Identical. No additional risks
Indications for Use	The bite away® neo 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.	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.	Indicated for same insect bites. Absence of mechanism of action claims does not affect safety or efficacy. No additional risks
Design	Hand held device that heats a ceramic disc with a resistor to temperatures of 51.5°C	Hand held device that heats a ceramic disc with a resistor to temperatures of 51.5°C	Identical Maximum No additional risks Temperature

	Subject Device	Predicate Device (K160943)	Rationale for no Effect on Safety and Efficacy
	bite away® neo	**bite away**	
Operator Directed/Applied to the Skin	Yes	Yes	Identical. No additional risks
Dry Weight	40 grams	25 grams	Weight does not play a role in the delivery of heat. Insignificant difference; essentially undetectable by user
Weight with batteries	86 grams	Not publicly available	Weight does not play a role in the delivery of heat. Insignificant difference; essentially undetectable by user
Duration of Use	3 and 5 seconds	3 and 6 seconds	Greater safety with less heating time
Dimension of Heated Area on the Device	7 mm	9 mm	Identical temperature range; no additional risk. . Small disc size delivers heat to less surface area; reducing risk. User can apply to multiple areas for more surface area treatments.
Temperature Range (device surface)	50 - 53°C	50 - 53°C	Identical temperature range. No additional risks
Temperature max at skin surface	48.6°C	Not publicly available	Ceramic pad touching skin is identical. Min. and max. temperature output from device deliver same heat to the skin.
Power Source	AA Batteries	AA Batteries	Identical. No additional risks
Voltage	3 volts DC	3 volts DC	Identical. No additional risks
Energy Transfer Source	Heated ceramic disc	Heated ceramic disc	Identical. No additional risks
Hard Plastic Outer Case	Yes	Yes	Identical. No additional risks
LED Light	Yes	Yes	Identical. No additional risks
Audible Signal	Yes	Yes	Identical. No additional risks
Microprocessor	Yes	Yes	Identical. No additional risks
Placed Directly on Insect Bite for Treatments	Yes	Yes	Identical. No additional risks
Classification Name	Powered Heating Pad	Powered Heating Pad	Identical. No additional risks
OTC Use	Yes	Yes	Identical. No additional risks
Product Class	2	2	Identical. No additional risks
Product Code	IRT	IRT	Identical. No additional risks
CFR Section	890.5740	890.5740	Identical. No additional risks
Intended Use	Delivery of mild heat to the skin/dermis	Delivery of mild heat to the skin/dermis	Identical. No additional risks

VII. PERFORMANCE DATA

Biocompatibility Testing
The patient contact polymers and ceramics were evaluated against the international standard ISO 10993-1 (Biological Evaluation of Medical Devices) and the FDA Guidance Document entitled, "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process." The battery of testing included:

Cytotoxicity
Sensitization
Irritation

Electrical Safety and Electromagnetic Compatibility (EMC)
Electrical safety and EMC testing were conducted on the bite away neo® device, consistent with the appropriate sections of the following electrical standards: IEC 60601-1 (MOD), IEC 60601-1-2, and IEC 60601-1-11. The bite away neo® device complies with IEC 60601-1 (MOD) standard for safety, IEC 60601-1-2 standard for EMC compliance, and IEC 60601-1-11 standard for medical electrical equipment in a home healthcare environment.

Software Verification and Validation
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software would not directly result in serious injury or death to the patient or operator. The bite away neo device complies with the applicable sections of IEC 62366.

Usability Studies
Usability testing was conducted on the bite away neo® device consistent with the appropriate sections of the following usability standards: IEC 60601-1-6. The bite away neo® device complies with the applicable sections of IEC 60601-1-6.

Clinical Studies
No clinical studies were performed to support safety or effectiveness of the subject device.

VIII. CONCLUSIONS
The nonclinical testing demonstrates that the subject device is as safe and effective, and performs as well as or better than the legally marketed predicate device.