September 12, 2025

MibeTec, GmbH
Oliver Grunert
Head of Development, Production, Regulatory and Quality
Münchener Str. 15
Brehna, 06796
Germany

Re: K250047
Trade/Device Name: bite away two
Regulation Number: 21 CFR 890.5740
Regulation Name: Powered Heating Pad
Regulatory Class: Class II
Product Code: IRT
Dated: August 1, 2025
Received: August 12, 2025

Dear Oliver Grunert:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Amber T. Ballard -S

Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation and
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OHT5: Office of Neurological and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250047

Device Name
bite away® two

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

Date Prepared: September 12, 2025

I. SUBMITTER

Manufacturer Name:

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Brehna, Germany
D-06796
Telephone +49 34954 247 489

Mfg. Establishment Registration Number: 3015733772

Official Contact: Oliver Grunert
Head of Development, Production, Regulatory and Quality
mibetec.regulatory@dermapharm.com

II. DEVICE NAME

Name of Device:	bite away® two
Common or Usual Name:	Powered Heating Pad
Classification Name:	Pad, Heating, Powered (21 CFR 890.5740)
Regulatory Class	2
Product Code	IRT
510(k) Identification	K250047

III. PREDICATE DEVICE

bite away® neo (K220514)

IV. DEVICE DESCRIPTION

The mibeTec bite away® two device is a light weight, portable, handheld, 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 error message 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. As in any user-controlled heat therapy, the user determines the tolerance to such delivered heat

and applies and removes the heat treatment per their own tolerance; thereby virtually alleviating the risks of inadvertent overheating of the skin. The short duration of treatment time of 3 and 5 seconds and the small surface area of the 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 mibeTec bite away® two device utilizes two AAA batteries (1.5 volts each) that power a MOSFET that heats a 7mm ceramic disc to approx. 51°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 5 seconds of heating). The device consists of a few major components: a hard plastic outer case, a printed circuit board, two activation buttons, two AAA batteries, and a heated ceramic plate that contacts the patient.

Material Composition

The mibeTec bite away® two 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® two 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The bite away® two device shares indications for use and design principles with the following predicate devices: bite away® neo (K220514), a Class II medical device that was cleared for marketing in the United States under K220514.

Indications for Use

The bite away® two device and the bite away® neo (K220514) predicate device are substantially equivalent with respect to their indications for use as they are both indicated for the delivery of mild heat to the skin/dermis to provide temporary relief of the pain and itching resulting from insect stings and bites such as bees, wasps and mosquitoes.

Additionally, bite away® two and the bite away® neo device share indication for use principles of being OTC (over the counter).

SUMMARY: TABLE OF SUBSTANTIAL EQUIVALENCE

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

	Subject Device	Predicate Device	Substantially Equivalent
	mibeTec, GmbH bite away® two	**mibeTec, GmbH bite away® neo**	
Illustration			
510(k) Number	K250047	K220514	
Intended Use	Delivery of mild heat to the skin/dermis	Delivery of mild heat to the skin/dermis	Identical
Indications for Use	The bite away® two 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® 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.	Identical
Design	Handheld device that heats a ceramic disc with a resistor to temperatures of 51°C	Handheld device that heats a ceramic disc with a resistor to temperatures of 51.5°C	Yes
Temperature range of Skin surface	45.8 °C – 46.7 °C	not publicly available	Yes
Temperature Range (device surface)	50 °C – 53 °C	50 °C – 53 °C	Yes
max. Temperature of Skin surface	47.1 °C	48.6 °C	Yes
Operator Directed/Applied to the Skin	Yes	Yes	Yes
Dry Weight	32 grams	40 grams	Yes
Weight with batteries	55 grams	86 grams	Yes
Duration of Use	3 and 5 seconds	3 and 5 seconds	Yes
Dimension of Heated Area on the Device	6 mm	7 mm	Yes
Power Source	AAA Batteries	AA Batteries	Yes
Voltage	3 volts DC	3 volts DC	Yes
Energy Transfer Source	Heated ceramic disc	Heated ceramic disc	Yes
Hard Plastic Outer Case	Yes	Yes	Yes
LED Light	Yes	Yes	Yes
Audible Signal	Yes	Yes	Yes
Microprocessor	Yes	Yes	Yes
Placed Directly on Insect Bite for Treaments	Yes	Yes	Yes
Classification Name	Powered Heating Pad	Powered Heating Pad	Yes
OTC Use	Yes	Yes	Yes
Product Class	2	2	Yes

Product Code	IRT	IRT	Yes
CFR Section	890.5740	890.5740	Yes

VII. PERFORMANCE TESTING

Non-Clinical Testing

Biocompatibility Testing

The mibeTec bite away® two device was evaluated against the FDA Guidance document entitled "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices – Part 1: Evaluation of Testing within a Risk Management Process." The battery of testing included:

- Cytotoxicity – ISO 10993-5
- Sensitization – ISO 10993-10
- Irritation – ISO 10993-23

The device meets the requirements therein.

Electrical Safety

The mibeTec bite away® two device demonstrated compliance with the appropriate sections of the following electrical safety standards:

- IEC 60601-1:2005/AMD 1: 2012/AMD2:2020
- IEC 60601-1-6: 60601-1-6:2010/AMD1:2013/AMD2:2020
- IEC 62366: 62366-1:2015/AMD1:2020
- IEC 60601-1-11:2015/AMD1:2020

The device meets the requirements therein.

Electromagnetic Compatibility

The mibeTec bite away® two device demonstrated compliance with the appropriate sections of the following electromagnetic compatibility standards:

- IEC 60601-1-2:2014/AMD1:2020
- IEC TR 60601-4-2:2016

The device meets the requirements therein.

Software Validation and Verification

The software features of the mibeTec bite away® two device have been tested for functionality. The sequence of events under normal operating conditions has been verified and all features have been demonstrated to work properly. Furthermore, all error messages have been verified to operate properly when each programmed fault is triggered.

The bite away® two device was evaluated for thermal delivery characteristics to demonstrate that it performs as intended.

Clinical Testing

Clinical testing was not required to demonstrate safety and efficacy.

VIII. CONCLUSION

The non-clinical testing demonstrates that the subject device is as safe and effective and performs as well as the legally marketed predicate device.