April 29, 2019

AdDent, Inc.
Joshua Friedman
President
43 Miry Brook Road
Danbury, Connecticut 06810

Re: K182017
Trade/Device Name: Compex HD
Regulation Number: 21 CFR 872.6100
Regulation Name: Anesthetic Warmer
Regulatory Class: Class I
Product Code: QGO
Dated: January 25, 2019
Received: January 30, 2019

Dear Joshua Friedman:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182017

Device Name
Compex HD

Indications for Use *(Describe)*

The Compex HD is intended to be used by a dentist or health care provider to warm and dispense dental composite materials contained in a compule or PLT (Pre Loaded Tip) to 155 degrees F (68 degrees C).

Federal law restricts this device for sale to a licensed professional.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (k) SUMMARY

Owner/Submitter's Name: Joshua Friedman, D.D.S., AdDent, Inc.

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Contact Person: Joshua Friedman

Email: jfriedman@addent.com

Device Name: Compex HD

Common Name: Composite Warmer

Classification Name: Anesthetic warmer (21 CFR 872.6100) Product Code QGO

Marketed Device of Equivalence: Calset composite heater, 510(k) # K061395, Classification product code: EBZ (Activator, Ultraviolet, For Polymerization, 21 CFR 872.670), Subsequent product codes: EEG (Heat Source For Bleaching Teeth, 21 CFR 872.6475), EFC (Anesthetic warmer, 21 CFR 872.6100).

Prior Submission for this device: FDA 510(k): #K180062

Description of the Device:

Background: The traditional method of dispensing dental composite contained in a PLT (Pre-Loaded Tip) or compule is to use a mechanical composite dispensing device. The compule is loaded into the tip of the dispenser and hand applied mechanical force is used to extrude the material to the prepared dental cavity. Dispensing these materials at room temperature can be difficult due to their viscous nature. The Compex HD heats the composite material contained in the compule prior to use. The heated composite exhibits improved flow and is dispensed more easily. Composite materials are used to repair or restore teeth in the general population, but are not an integrated part of this device. In addition, research shows that pre-heating composite prior to light curing also improves depth of cure, shortens time of cure along with many other improved physical properties.

General Description: The Compex HD uses a heating device to elevate the temperature of dental composite material contained in a compule (PLT) to allow it to flow and be easily extruded. It utilizes a plastic housing in the shape of a traditional dispensing gun. The housing contains a heater element(s) and/or an electrically conductive plastic compule that itself acts as a heater when a current is applied. A control circuit board assembly and rechargeable lithium Ion battery are used to apply power to the heater. A separate wall plug-in USB power supply is used to charge the battery. The unit will not function with the USB power supply connected to the unit.

Indications for Use (Intended Use) Compex HD: The Compex HD is intended to be used by a dentist or health care provider to warm and dispense dental composite materials contained in a compule or PLT (Pre Loaded Tip) to 155˚F (68˚C).

Indications for Use (Intended Use) Calset Predicate Device: The Calset unit is used to warm dental composite materials and whitening bleach to 130°F (54°C) or 155°F (68°C). It is also used to warm anesthetic carpules to 98°F (37°C) (body temperature).

Indications for Use comparison – Calset predicate device vs. Compex HD		
	Calset (predicate)	**Compex HD**
Indications for Use (exact wording)	**"The Calset unit is used to warm dental composite materials and whitening bleach to 130°F (54°C) or 155°F (68°C). It is also used to warm anesthetic carpules to 98°F (37°C) (body temperature)."**	**"The Compex HD unit is intended to be used by a dentist or health care provider to warm and dispense dental composite materials contained in a compule or PLT (Pre Loaded Tip) to 155˚F (68˚C)."**
Dental application	Yes – **"The Calset unit is used to warm dental composite materials"**	Yes – **"The Compex HD unit is intended to be used by a dentist or health care provider to warm and dispense dental composite materials"**
Used to directly dispense composite material contained in a compule (PLT)	No – composite material are dispensed indirectly using standard mechanical handheld dispensers - refer to explanation and figures below this chart*	Yes – **"to warm and dispense dental composite materials contained in a compule or PLT (Pre Loaded Tip)"**
Number of temperature settings	Three – **"dental composite materials and whitening bleach to 130°F (54°C) or 155°F (68°C). It is also used to warm anesthetic carpules to 98°F (37°C)"**	One – **"to warm and dispense dental composite materials contained in a compule or PLT (Pre Loaded Tip) to 155˚F (68˚C)."**
Temperatures settings	**"98°F (37°C), 130°F (54°C), 155°F (68°C)"**	**"155°F (68°C)"**
Used to warm dental composite materials	Yes - **"The Calset unit is used to warm dental composite materials and whitening bleach to 130°F (54°C) or 155°F (68°C)"**	Yes **– "The Compex HD unit is intended to be used by a dentist or health care provider to warm and dispense dental composite materials contained in a compule or PLT (Pre Loaded Tip) to 155˚F (68˚C)."** The temperature option of 130°F (54°C) is not included in the Compex HD as it is no longer commonly used to heat composite materials.
Used to warm anesthetic carpules	Yes - **"It is also used to warm anesthetic carpules to 98°F (37°C)"** The Calset uses a specially designed tray that accepts anesthetic carpules.	No - The Compex HD unit is by design not intended to accept anesthetic carpules and therefore this feature is eliminated. It will only accept dental materials contained in compules or PLT (Pre Loaded Tip).
Used to warm whitening bleach	Yes - **"The Calset unit is used to warm dental composite materials and whitening bleach to 130°F (54°C) or 155°F (68°C)"** Although the Calset is designed to warm whitening bleach, this is no longer a common practice.	No - The Compex HD unit is by design not intended to heat whitening bleach and therefore this feature is eliminated. It will only accept dental materials contained in compules or PLT (Pre Loaded Tip).

* With the table top Calset predicate device, the compule containing the composite material (PLT) is loaded in a standard handheld composite dispenser which is then inserted into a pre-heated tray (holster) that sits on top of the Calset heater base. Once the compule reaches the desired application temperature of 155°F (68°C) in approximately three minutes, the dispenser with loaded compule is removed from the heated tray (holster) and the heated composite material is dispensed to the patient.

With the Compex HD unit, the heater is integrated into the front of the dispenser. This is in the form of a heating element, or alternatively the compule itself is made from electrically conductive plastic and acts a heating element. The compule (PLT) containing the composite material is loaded in the front of the unit. The heater is activated by a push button switch on the control panel. Once the unit reaches operating temperature of approximately 155°F (68°C), a LED light changes color to indicate that the material is ready to be dispensed directly to the patient. See figure 1.

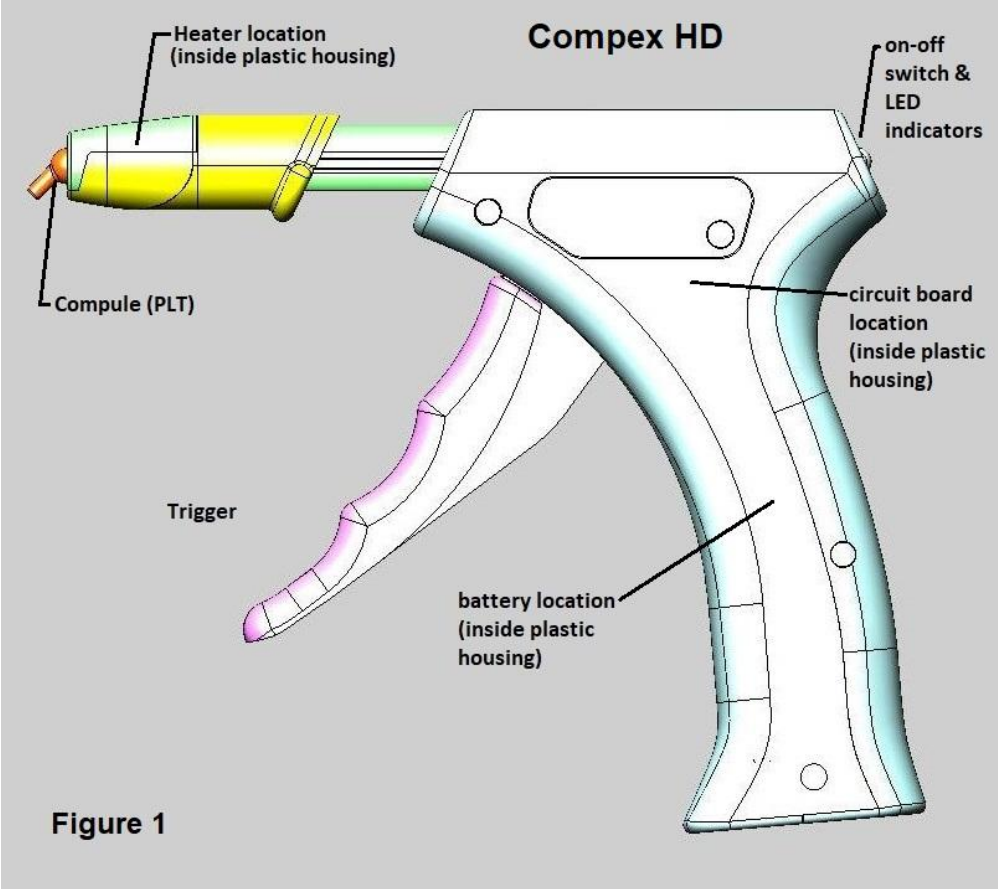

Figure 1

Technical Characteristics of the Compex HD compared to the Predicate Device:

Technical Characteristics – Calset predicate device vs. Compex HD		
	Calset (predicate)	**Compex HD**
Device Configuration	Table Top	Hand Held
Heater element	yes	yes
Uses removable trays configured for different composite dispensers	yes	no
Uses hand mechanical force to dispense composite	yes	yes
Power supply	low voltage detachable wall plug-in power supply	low voltage Li-Ion Battery/ low voltage detachable wall plug-in power supply used to charge battery
Unit operates while connected to mains power supply	Yes - required	No – will not operate
Control circuit board	yes	yes
Microprocessor control	yes	yes
Temperature control	thermistor	thermistor
Number of temperature settings	3	1
Temperatures settings	98°F (37°C), 130°F (54°C), 155°F (68°C)	155°F (68°C)
Push button control	yes– on/off and temperature selection	yes– on/off
LED indicators	indicate temperature selection and when operating temperature is reached	indicate when operating temperature is reached and battery charge status
Used to warm anesthetic carpules	yes	no
Used to warm whitening bleach	yes	no
Primary housing material	molded plastic	molded plastic
Other materials (excluding battery)	aluminum/rubber	stainless steel
Factory temperature calibration	yes	yes
Disinfection procedure	yes – wiped with cloth	yes – wiped with cloth
Patient applied part	no	yes
Biocompatible material(s)	not required	yes

Discussion: The Compex HD unit performs the same function as the predicate Calset device – to warm composite materials to 155°F (68°C) prior to dispensing the material used to repair the patient's teeth. In both applications the heated composite becomes less viscous and flows more easily, and therefore is dispensed more easily with less physical effort and more control. The Calset must be used with a separate mechanical dispenser such as the CoMax (product code KXR Applicator, Resin, Exempt), also made by AdDent, Inc. The Compex HD dispenses material directly. In one version of the Compex HD the compule containing composite is warmed by being in close proximity to one or more PTC (Positive Temperature Coefficient) electrical heating elements. In another version of the Compex HD the compule itself is molded from electrically conductive plastic that itself becomes a heater when a current is applied to the compule. Unlike the Calset, the Compex HD is not designed to warm or dispense anesthetic solution or whitening bleach, and as a result does not require the other two temperature settings of 98°F (37°C), and 130°F (54°C).

Non-Clinical performance data: To demonstrate that the Compex HD and Calset predicate device are substantially equivalent, testing was performed on both devices using thermocouples inserted into composite filled compules to determine the temperature of the composite during heating. The test results demonstrate that both devices heat the composite to a temperature of approximately 155°F (68°C). Refer to Appendix B Product Tests, Test Report # 131 and Test Report # 165 for test results.

In addition, both the Calset predicate unit and the Compex HD have been tested and successfully passed the following international standards (refer to Appendix C Product Safety and EMC Test Reports:

- American National Standard/International Standard ANSI/AAMI/IEC 60601-1, "Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance (Third Edition, Amendment 1 2012)."

- American National Standard/International Standard ANSI/AAMI/IEC 60601-1-2, "Medical Electrical Equipment, Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests, 4th Ed. (2014)."

Clinical performance data: Not Applicable.

Performance data summary: The non-clinical test results demonstrate that the Compex HD and predicate Calset essentially perform the same function – to heat dental composite material contained in a compule (PLT) to approximately 155°F (68°C).

In addition, the process of dispensing the composite material is similar in that the Calset is used with a separate handheld dispenser to hold the compule while it is being heated and then dispensed while the Compex HD has this feature incorporated into a single device.

Since there is no difference in the temperature of the applied composite material and the process of dispensing the composite is similar, requiring fewer steps and less time with the Compex HD, the unit is as safe and effective as the predicate Calset device.

Elimination of the additional temperature settings of 98°F (37°C), and 130°F (54°C) as featured on the predicate Calset device presents no additional safety hazard. The Compex HD unit is not intended to heat anesthetic carpules or whitening bleach and the physical design of the Compex HD is incompatible with these materials. Use of the 130°F (54°C) temperature setting with composite materials is no longer common.

In addition the safety of the Compex HD is demonstrated by successfully passing the required safety and EMC standards referenced above in Non-clinical performance data.