January 14, 2020

Synapse Dental
℅ Valerie Defiesta-Ng
Vice President, Regulatory Affairs
Experien Group, LLC
224 Airport Parkawy, Suite 250
San Jose, California 95110

Re: K192429
Trade/Device Name: Dental Pain Eraser
Regulatory Class: Unclassified
Product Code: LWM
Dated: December 16, 2019
Received: December 17, 2019

Dear Valerie Defiesta-Ng:

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 Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192429

Device Name
Dental Pain Eraser DPE-T300

Indications for Use *(Describe)*
The Dental Pain Eraser DPE-T300 is intended to provide temporary dental anesthesia (pain relief). It is intended for prescriptive use only for the alleviation of oral pain for use by pediatric (10 years through 22 years of age) and adult patients for treatment at home. Pediatric patients 10 through 12 years of age must be supervised by an adult.

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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510(k) SUMMARY

510(k) Notification K192429

GENERAL INFORMATION [807.92(a)(1)]

Applicant:
Synapse Dental
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Cranston, RI 02920
USA
Phone: 401-932-9877
Fax: 401-464-8903

Contact Person:
Valerie Defiesta-Ng
Vice President, Regulatory Affairs
Experien Group, LLC
224 Airport Parkway, Suite 250
San Jose, CA 95110
USA

Date Prepared: January 13, 2020

DEVICE INFORMATION [807.92(A)(2)]

Trade Name:
Dental Pain Eraser DPE-T300

Generic/Common Name:
Device, Electrical Dental Anesthesia

Classification:
Unclassified, Pre-Amendment

Product Code:
LWM

PREDICATE DEVICE(S) [807.92(A)(3)]

Dental Pain Eraser DPE-C300 (K182947)

DEVICE DESCRIPTION [807.92(A)(4)]

The Dental Pain Eraser DPE-T300 is a non-invasive electrical stimulation device that is used to numb the nerve pain associated with orthodontic procedures and to dull the pain of canker sores often developed inside the mouths of patients wearing braces or retainers. This method of treatment is referred to as Transcutaneous Electrical Nerve Stimulation (TENS).

The Dental Pain Eraser DPE-T300 has a shape and size similar to a common toothbrush, except that in place of the bristles are two metal electrodes. In operation, the device is turned on for 30

seconds to 10 minutes, the two electrodes are rubbed gently up and down the gums above the patient's aching tooth or on the intact skin around the canker sore. Current flowing between the electrodes through the gum anesthetizes the nearby nerves thus alleviating pain. The Dental Pain Eraser is for the alleviation of oral pain for pediatric (10 years through 22 years of age) and adult patients for treatment at home who are under the care of a dental/orthodontic professional. Pediatric patients 10 through 12 years of age must be supervised by an adult.

INDICATIONS FOR USE [807.92(a)(5)]

The Dental Pain Eraser DPE-T300 is intended to provide temporary dental anesthesia (pain relief). It is intended for prescriptive use only for the alleviation of oral pain for use by pediatric (10 years through 22 years of age) and adult patients for treatment at home. Pediatric patients 10 through 12 years of age must be supervised by an adult.

SUBSTANTIAL EQUIVALENCE

The Dental Pain Eraser DPE-T300 is substantially equivalent to the predicate device with regard to function and physical characteristics. Any differences in the technological characteristics between the devices do not raise any different issues of safety or effectiveness. Thus, the proposed Dental Pain Eraser DPE-T300 is substantially equivalent to the predicate device.

PERFORMANCE DATA [807.92(b)]

All necessary bench and usability testing were conducted on the Dental Pain Eraser to support a determination of substantial equivalence to the predicate device.

[807.92(b)(1)] Nonclinical Testing Summary

Synapse performed safety testing in accordance with IEC 60601-1-11, Edition 2.0, 2015-01, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard Requirements for medical electrical equipment and medical electrical systems use in the home healthcare environment* demonstrating basic safety and essential performance for the lay or the trained healthcare personnel. In addition, the Dental Pain Eraser DPE-T300 was tested for ingress protection (IP) code IP24 in accordance with IEC 60529, Edition 2.2, 2013-08, *Degrees of protection provided by enclosures (IP code)*.

[807.92(b)(2)] Clinical/Usability Testing Summary

Human factors usability testing was conducted to additionally confirm that representative users can use the device safely and effectively without supervision from a healthcare professional. This testing was performed in accordance with recommendations in FDA's Guidance Document titled, "*Applying Human Factors and Usability Engineering to Medical Devices*," issued February 03, 2016, and IEC 62366-1:2015, *Medical devices - Part 1: Application of usability engineering to medical devices*.

The Synapse Dental Pain Eraser (DPE-T300) underwent usability testing to demonstrate that the DPE-T300 could be used by representative users under simulated use conditions without producing patterns of failures that could result in negative clinical impact to patients or harm to users. The test also included verifying the Instructions for Use, packaging, and labeling for effectiveness and ensuring that the use-related risks of the DPE-T300 were mitigated. Synapse initially proposed that the DPE-T300 be indicated for pediatric patients 8 – 11 years of age with

parental supervision, pediatric patients 12 – 22 years of age without adult supervision, and adult patients. Therefore, the representative group used in this Usability study was fifteen (15) Adult (18 + years of age) and fifteen (15) Pediatric patients, of which fourteen (14) were Male and sixteen (16) were Female. Pediatric patients 8 – 11 years of age required parental/guardian supervision and patients 12 – 17 years of age were asked to work with their guardian to the degree they would at home. Each participant was given a realistic task scenario to perform with the DPE-T300 on an anatomical model. The participants were rated on task completion performance, interviewed and asked follow-up questions about the task, and asked knowledge-based questions on the system documentation.

Overall, task completion rates were high for removing the device from the package, holding the device in the correct orientation, turning on the device, moving the electrodes in the recommended motion/around affected area, and removing the electrodes after the recommended duration. The tasks that most patients completed with issues or did not complete were clearing excess moisture or saliva from gums, cleaning the entire device, and ensuring the blue indicator light is pulsing to signal device is ready for use. None of the observed task errors, close calls, or failures fell into the category of undesirable or intolerable risk. The majority of the use-related risk errors were related to the IFU layout and organization. Many use errors were attributed to patients not reading the IFU or having difficulty picking out particular instructions or warnings. While serious use errors were committed, the likelihood of occurrence for these are incredible and further reduction of the residual risk is not possible or practical, and the device's benefits outweigh its residual risks. The pre-screening and training by the dentist/orthodontist that occurs with the prescription of the device will also further lower the potential for harm. The test results indicate that the goals of the validation studies were met and that the use-related safety issues associated with the DPE-T300 have been adequately mitigated, and no new risks have been identified.

CONCLUSION [807.92(B)(3)]

Extensive nonclinical and usability testing has been performed on the Dental Pain Eraser to evaluate the overall performance of the device. The collective results confirm that the Dental Pain Eraser meets its specifications and exhibits the required characteristics for its intended use in alleviating pain and as such is substantially equivalent to the predicate device. The Dental Pain Eraser DPE-T300 is substantially equivalent to the predicate device.

Table 1: Substantial Equivalence Table

Characteristic	Dental Pain Eraser DPE-T300 (Proposed Device)	Dental Pain Eraser DPE-C300 (Predicate Device)	Rationale for Substantial Equivalence
510(k) Number	TBD	K182947	--
Indications for Use	The Dental Pain Eraser DPE-T300 is intended to provide temporary dental anesthesia (pain relief). It is intended for prescriptive use only for the alleviation of oral pain for use by pediatric (10 years through 22 years of age) and adult patients for treatment at home. Pediatric patients 10 through 12 years of age must be supervised by an adult.	The Dental Pain Eraser DPE-C300 is intended to provide temporary dental anesthesia (pain relief) and is indicated for use before, during, or after dental and orthodontic procedures, and other sources of oral pain. It is intended for use by dental/orthodontic professionals for the alleviation of oral pain.	The change in Indications for Use statement does not raise different questions of safety and effectiveness and is supported by the appropriate IEC 60601-1-11 and usability testing.
Intended User or Patient Population	The Dental Pain Eraser is for the alleviation of oral pain for use by pediatric (10 years through 22 years of age) and adult patients for treatment at home who are under the care of a dental/orthodontic professional. Pediatric patients 10 through 12 years of age must be supervised by an adult.	The Dental Pain Eraser is intended for use by dental/orthodontic professionals for the alleviation of oral pain in their pediatric (10 years through 22 years of age) and adult patients.	The change in Intended Use does not raise different questions of safety and effectiveness and is supported by the appropriate IEC 60601-1-11 and usability testing.
Use Environment	Home	Professional Dental/Orthodontic Facility	The difference in use environment does not raise different questions of safety and effectiveness and is supported by the usability testing.
Product Code	LWM	LWM	N/A (same)
Classification	Unclassified, Pre-amendment	Unclassified, Pre-amendment	N/A (same)
Manufacturer	Synapse Dental	Synapse Dental	N/A (same)
Power Source(s)	Three 393/309 Silver Oxide Button Cell Batteries	Three 393/309 Silver Oxide Button Cell Batteries	N/A (same)
• Method of Line Current Isolation	Not connected to the line	Not connected to the line	N/A (same)

Table 1: Substantial Equivalence Table (Cont.)

Characteristic	Dental Pain Eraser DPE-T300 (Proposed Device)	Dental Pain Eraser DPE-C300 (Predicate Device)	Rationale for Substantial Equivalence
Patient Leakage Current			
○ Normal Condition (µA)	DC ~ 0µA AC<10mA	DC ~ 0µA AC<10mA	N/A (same)
○ Single Fault Condition (µA)	DC ~0µA AC<10mA	DC ~0µA AC<10mA	
Average DC current through electrodes when device is on but no pulses are being applied (µA)	0µA	0µA	N/A (same)
Number of Output Modes	1 (As requested per Q180245, see Table 2 for the Output Specifications)	1 (As requested per Q180245, see Table 2 for the Output Specifications)	
Number of Output Channels	2	2	
• Synchronous or Alternating?	Alternating	Alternating	
• Method of Channel Isolation	Not isolated	Not isolated	
Regulated Current or Regulated Voltage?	Voltage	Voltage	
Software/Firmware/ Microprocessor Control?	Firmware	Firmware	
Automatic Overload Trip?	No	No	
Automatic No-Load Trip?	No	No	
Automatic Shut Off?	Yes	Yes	
User Override Control?	Yes	Yes	

Table 1: Substantial Equivalence Table (Cont.)

Characteristic	Dental Pain Eraser DPE-T300 (Proposed Device)	Dental Pain Eraser DPE-C300 (Predicate Device)	Rationale for Substantial Equivalence
Indicator Display			
• On/Off Status?	Yes	Yes	N/A (same)
• Low Battery?	No	No	N/A (same)
• Voltage/Current Level?	No	No	
Timer Range (minutes)	5 minutes Max	5 minutes Max	N/A (same)
Compliance with Voluntary Standards	Compliant with applicable requirements of: IEC 60529, IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, IEC 60601-2-10, IEC 62304 ANSI/AAMI NS4:2013 – *Transcutaneous Electrical Nerve Stimulators* ISO 7405: Second edition 2008-12-15 *Dentistry - Evaluation of biocompatibility of medical devices used in dentistry* [Including: Amendment 1 (2013)]. ISO 10993-1:2009 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*	Compliant with applicable requirements of: IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62304 ANSI/AAMI NS4:2013 – *Transcutaneous Electrical Nerve Stimulators* ISO 7405: Second edition 2008-12-15 *Dentistry - Evaluation of biocompatibility of medical devices used in dentistry* [Including: Amendment 1 (2013)]. ISO 10993-1:2009 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*	Synapse has verified the Dental Pain Eraser is compliant to the most current applicable standards. The addition of IEC 60601-1-11 was performed for home healthcare use.

Table 1: Substantial Equivalence Table (Cont.)

Characteristic	Dental Pain Eraser DPE-T300 (Proposed Device)	Dental Pain Eraser DPE-C300 (Predicate Device)	Rationale for Substantial Equivalence
Compliance with Voluntary Standards (continued)	IEC 62366-1:2015, *Medical devices. Part 1: Application of usability engineering to medical devices* ISO 14971:2012, *Medical Devices. Application of Risk Management to Medical Devices*	IEC 62366-1:2015, *Medical devices. Part 1: Application of usability engineering to medical devices* ISO 14971:2012, *Medical Devices. Application of Risk Management to Medical Devices*	N/A (same)
Compliance with 21 CFR 898?	Not applicable	Not applicable	--
Weight (oz.)	0.423oz	0.423oz	N/A (same)
Unit Body Dimensions (in.) Two Electrode Probes: Dimensions (in.)	Pen-shaped ~0.5" to ~1.04" Dia., Length ~6.27" 0.118" Dia., 0.157", Center to center spacing	Pen-shaped ~0.5" to ~1.04" Dia., Length ~6.27" 0.118" Dia., 0.157", Center to center spacing	
Materials and Construction			
• Patient Contacting Materials Within the Mouth	Tip Assembly with Electrodes: • Lustran 348 WT012002 (ABS) • Clariant SB7M665060, GREY • 303 Stainless Steel	Tip Assembly with Electrodes: • Lustran 348 WT012002 (ABS) • Clariant SB7M665060, GREY • 303 Stainless Steel	N/A (same)
• Biocompatible	Biocompatibility testing was performed per ISO 10993-1 and FDA Guidance Document, "*Use of 10993-1, 'Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'*," issued June 16, 2016	Biocompatibility testing was performed per ISO 10993-1 and FDA Guidance Document, "*Use of 10993-1, 'Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'*," issued June 16, 2016	
Ingress Protection Rating	IP24	IP21	The IP24 rating is appropriate for home use. This difference does not raise different questions of safety and effectiveness.

Table 2: Comparison of Output Specifications

Description		Dental Pain Eraser DPE-T300 (Proposed Device)	Dental Pain Eraser DPE-C300 (Predicate Device)
Mode or Program Name		Only one Mode	Only one Mode
Indication for Use		Pulsing Light	Pulsing Light
Waveform (e.g., pulsed monophasic, biphasic)		Complex, Biphasic, Charge Neutral (See Detailed Description)	Complex, Biphasic, Charge Neutral (See Detailed Description)
Shape (e.g., rectangular, spike, rectified sinusoidal)		Rectangular	Rectangular
Pole Configuration (e.g., 2-pole, 4-pole) – For interferential current only		NA	NA
Maximum Output Voltage (V) (+/- 10%)		2.08@ 500Ω	2.08@ 500Ω
		2.74@ 1kΩ	2.74@ 1kΩ
		4.24@ 10kΩ	4.24@ 10kΩ
Maximum Output Current (mA) (+/-10%)		4.16@ 500Ω	4.16@ 500Ω
		2.74@ 1kΩ	2.74@ 1kΩ
		0.42@ 10kΩ	0.42@ 10kΩ
Duration of primary (depolarizing) phase (ms)			
High Frequency Pulse duration (µs)		50µs on, 50µs off	50µs on, 50µs off
High Frequency (Hz) [or Rate (pps)]		10kHz	10kHz
	Slow Frequency Pulse Duration	1Hz	1Hz
For multiphasic waveforms only:	Symmetrical phases?	Yes	Yes
	Phase Duration (include units), (state range, if applicable), (both phases, if asymmetrical)	0.999s	0.999s
Net Charge (microcoulombs (µC) per cycle) (If zero, state method of achieving zero net charge.)		0µC. Positive current through the load for 0.999s, then negative going current for 0.999s and repeat	0µC. Positive current through the load for 0.999s, then negative going current for 0.999s and repeat

Table 2: Comparison of Output Specifications (Cont.)

Description		Dental Pain Eraser DPE-T300 (Proposed Device)	Dental Pain Eraser DPE-C300 (Predicate Device)
Maximum Phase Charge (µC)		2.77µC @1kΩ	2.77µC @1kΩ
Maximum Current Density (mA/cm^2, r.m.s.)		68.5mA/cm^2 @1kΩ, assuming 4mm^2 electrode contact area	68.5mA/cm^2 @1kΩ, assuming 4mm^2 electrode contact area
Maximum Average Current (average absolute value – mA)		0mA @1kΩ	0mA @1kΩ
Maximum Average Power Density (W/cm^2), (using smallest electrode conductive surface area)		0.187W/cm^2 @1kΩ	0.187W/cm^2 @1kΩ
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	15	15
	(b) Bursts per second	333	333
	(c) Burst duration (seconds)	3ms	3ms
	(d) Duty Cycle: Line (b) x Line (c)	0.999s	0.999s
ON Time (seconds)		0.2498s	0.2498s
OFF Time (seconds)		0.7493s	0.7493s
Additional Features (specify, if applicable)		Device can be turned off by the user or it turns off automatically after 5 minutes, whichever time is shortest	Device can be turned off by the user or it turns off automatically after 5 minutes, whichever time is shortest