August 30, 2022

Saliwell Ltd.
Andy Wolff
President
3A Hatamar St.
Harutzim, Israel 6091700
ISRAEL

Re: K220618
Trade/Device Name: SaliPen
Regulation Number: 21 CFR 872.5560
Regulation Name: Electrical salivary stimulatory system
Regulatory Class: Class II
Product Code: QTT
Dated: May 19, 2022
Received: May 25, 2022

Dear Andy Wolff:

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,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
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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)*
K220618

Device Name
SaliPen

Indications for Use *(Describe)*
SaliPen is an electrical salivary stimulator system, indicated for use in patients with xerostomia (dry mouth).

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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K220618

510(k) Summary

I. SUBMITTER

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Date of Summary preparation: February 2, 2022

II. DEVICE

Name of device: SaliPen

Common name: Electrical salivary stimulator system

Classification name: Electrical salivary stimulator system

Regulatory Class: II

Product Code: QTT

III. PREDICATE DEVICE

The predicate device is SaliPen, K180838.

IV. DEVICE DESCRIPTION

SaliPen is an electrical salivary stimulatory system device. It is comprised of two units: an intraoral stimulating unit and an extra-oral command unit. The latter includes an electronic circuit, a compartment containing a 3V coin battery, and a bottom for switching the stimulation "On" and "Off".

The stimulating unit is made of silicone rubber and includes a stem and two flexible arms. The stem is used to hold SaliPen between the lips. The flexible arms are shaped to the inner contour of the lower dental arch. Each arm carries one pair of gold-plated stimulating electrodes. The device is designed in a manner that allows placing the electrodes on the lingual mucosa in the mandibular third molar region. The lingual nerve, which runs closely to this location, is the target of the stimulation due to its crucial role in the salivary reflex.

Electrical stimulation is achieved by the delivery of low-power, low voltage, biphasic electrical pulses. The selected stimulating parameters provide effective stimulation, yet are well below the sensation thresholds, and definitely below the pain threshold.

The user turns the device "On" and afterwards places the device in his/her mouth. After up to five minutes of use, the user removes the device from his/her mouth and deactivates the

stimulation. The device is used not more than 5 times per day. The device and replacement devices are allowed for a cumulative use of up to 50 months.

Intended use:

SaliPen is an electrical salivary stimulator system, and is identified as an intraoral device intended to electrically stimulate a relative increase in saliva production.

V. INDICATIONS FOR USE

SaliPen is an electrical salivary stimulator system, indicated for use in patients with xerostomia (dry mouth).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Feature being compared	**SUBMISSION DEVICE** **SaliPen OTC device (K220618)**	**PREDICATE DEVICE** **SaliPen prescription device (K180838)**
Mechanism of action	Promote salivary function by mechanical and electrical stimulation of nerves that are involved in the salivary reflex.	Promote salivary function by mechanical and electrical stimulation of nerves that are involved in the salivary reflex.
Placement of electrodes	Positioned on the lingual mucosa in the mandibular third molar area in vicinity of the lingual nerve.	Positioned on the lingual mucosa in the mandibular third molar area in vicinity of the lingual nerve.
Electronics	Digital.	Digital.
Anatomical adaptation to the oral cavity	Yes, due to device flexibility.	Yes, due to device flexibility.
Frequency of use	Up to 5 times per day, 5 minutes at a time.	Up to 5 times per day, 5 minutes at a time.
External control	Microprocessor-based.	Microprocessor-based.

Summarizing, the similarities of the technological characteristics between the submission device and the predicate device include mechanism of action, placement of electrodes, electronics, frequency of use and external control. The difference between the submission device and the predicate device as to their availability (over-the-counter or prescription) does not raise concerns of safety and effectiveness in the OTC device.

VII. PERFORMANCE DATA

Nonclinical performance evaluation:

Testing (including electromagnetic compatibility, electrical safety, biocompatibility assessment, and risk analysis) was performed and found to be in compliance with the standards, such as ISO 10993-5, ISO 10993-12, EN ISO 14971:2012, EN 60601-1:2005, EN 60601-1-2:2007, IEC 60601-1-11:2010, ISO 15223-1:2016, EN 60529:1992+A2:2013, IEC 62304 1st edition 2006-05, EN ISO 13485:2003, and UL 1642.

Clinical performance evaluation:

A Human Factors validation trial was conducted in accordance with the FDA Guidance Document "Applying Human Factors and Usability Engineering to Medical Devices" from February 3, 2016. This trial showed that, based on the external label of the product, both study subjects with xerostomia (dry mouth) and subjects without this condition were able to decide correctly whether they are eligible or not, respectively, to using the device. Furthermore, the study results showed that study subjects who participated in using the device were able to follow the over-the-counter labeling instructions for use.

VIII. CONCLUSIONS

Based on intended use, technological characteristics, and performance testing, we conclude that the SaliPen OTC device is substantially equivalent to the SaliPen prescription device.