September 6, 2019

KEA Products Ltd.
% Robert Bock
Official Correspondent
Robert T. Bock Consultancy LLC
66 Drovers Lane
Brewster, New York 10509

Re: K181986
Trade/Device Name: Klinly Ultrasonic Tongue Cleaner
Regulation Number: 21 CFR 872.6865
Regulation Name: Powered Toothbrush
Regulatory Class: Class I
Product Code: QIA
Dated: August 7, 2019
Received: August 8, 2019

Dear Robert Bock:

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 Adjodha
Acting Assistant 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)*
K181986

Device Name

Klinly Ultrasonic Tongue Cleaner

Indications for Use *(Describe)*

The Klinly Ultrasonic Tongue Cleaner is indicated to reduce plaque, food debris, and bacteria from the surface of the tongue, and also to help fight bad breath and promote oral hygiene.

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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K181986

510(k) SUMMARY

Applicant: KEA Products Limited
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Application Correspondent: Robert T. Bock
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Date of summary prepared: September 6, 2019

Trade Name: Klinly Ultrasonic Tongue Cleaner

Regulation Description: Powered toothbrush

Regulation Number: 21 CFR 872.6865

Product code: QIA

Primary Predicate:

- Cybersonic (K980075)
  American Dentronics, Incorporated.

Reference Devices:

- Unik Tongue Cleaner (K983683)
  Unik Products, Inc.
- Sonex Ultrasonic Tooth Brush (K913724)
  Sonex International Corporation.
- Sonicare Advance Toothbrush, Model 4900 (K040416)
  Philips Oral Healthcare, Inc.

DEVICE DESCRIPTION:

The Klinly Ultrasonic Tongue Cleaner is a battery-operated device intended to be used to supplement daily oral hygiene care. It operates on two (2) AAA Alkaline batteries. All user-contacting components of the Klinly Ultrasonic Tongue Cleaner are constructed of injection-molded plastics which have demonstrated substantially equivalent biocompatibility according to ISO 10993-1.

The Klinly Ultrasound Tongue Cleaner device is comprised of three principles of operation to supplement daily oral hygiene by tongue cleaning. The device has a tongue scraping head, which:

(1) Operates manually as a standard manual tongue scraper
(2) Produces a low-frequency tactile vibration at 233 Hz, and
(3) Emits ultrasound pressure waves at 1.6 MHz frequency.

INDICATIONS FOR USE:

The Kinly Ultrasonic Tongue Cleaner is indicated to reduce plaque, food debris, and bacteria from the surface of the tongue, and also to help fight bad breath and promote oral hygiene.

COMPARISON OF INDICATIONS FOR USE:

SUBJECT DEVICE Klinly Ultrasonic Tongue Cleaner Indications for use	PRIMARY PREDICATE Cybersonic (K980075) Indications for use	REFERENCE DEVICE Unik Tongue Cleaner (K983683) Indications for Use
The Kinly Ultrasonic Tongue Cleaner is indicated to o reduce plaque, food debris, and bacteria from the surface of the tongue, and to help fight bad breath and promote oral hygiene.	Use to remove surface tongue debris, residue, plaque or filmy build-up that results from eating, drinking, smoking or other types of consumption which can lead to bad breath. Also may be used to remove salivary tongue plaques and residue that naturally accumulate during sleep or between cleanings.	To remove bacteria from and prevent plaque build-up on the tongue to help fight bad breath and promote oral hygiene.

The subject device Indications for Use includes an indication to reduce bacteria from the surface of the tongue, which is not found in the Primary Predicate Indications for Use. Additional differences in wording do not impact the substantial equivalence.

The Reference Device Unik Tongue Cleaner (K983683), is identified for this difference, as it is a manual tongue scraper indicated to remove bacteria (from the surface of the tongue).

Further reference devices used for technological comparisons do not include any component-specific language that would raise any concern related to the substantial equivalence of the subject device.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS :

Technological Characteristics	SUBJECT DEVICE Klinly Ultrasonic Tongue Cleaner	PRIMARY PREDICATE Cybersonic (K980075)
Scraping edge	Molded plastic (ABS) curved scraping edge, rounded	Molded plastic flat scraping edge
Scraping action	Manually operated scraping action (patient applies pressure as they are scraping to remove debris)	Same as Subject Device
Target Population	Adults and adolescents 12 years and older	Same as Subject Device
Anatomical sites	Surface of the tongue	Same as Subject Device
Intended use	reducing tongue debris	Same as Subject Device
Tactile vibration	Low-frequency (233 Hz)	None
Ultrasound pressure waves	1.6 Mz from piezoelectric transducer in the device	None
Energy source	two AAA (3.0 VDC) alkaline batteries	None

The subject device is similar to the primary predicate device as both devices are intended as a manual tongue scraper. Both devices are made from molded plastic and intended to be used on the surface of the tongue, operated manually by the patient (patient applies pressure to the device handle while scraping to remove debris). The subject device is different as it is powered by two AA batteries, which power and control the device, piezoelectric transducer for the low-frequency tactile vibrations, and electronics which generate the 1.6 MHz ultrasound pressure waves.

The reference device Sonicare Advanced Toothbrush (K040416) is different than the subject device as it is a powered toothbrush; however, it is also powered and generates low-frequency tactile vibrations (261 Hz), similar to the subject device.

The reference device Sonex Ultrasonic Toothbrush (K913724) is different than the subject device as it is a powered toothbrush; however, it is also similarly powered and generates the same ultrasound pressure waves as the subject device (at 1.6 Mhz).

Any small differences in the technological characteristics between the subject, primary predicate, and reference devices have been addressed through non-clinical performance testing and do not impact the substantial equivalence of the subject device.

NON-CLINICAL TESTING:

The Klinly Ultrasonic Tongue Cleaner has conducted the following testing to demonstrates substantial equivalence to the predicates according to the following:

Biocompatibility: Assessment per FDA Guidance - Biological Evaluation of medical devices – ISO 10993-1 including:

- Cytotoxicity Test according to ISO 10993-5: 2009, Biological evaluation of Medical Devices Part 5: Tests for In Vitro Cytotoxicity
- Sensitization Test according to ISO 10993-10:2010 Part 10: Test for irritation and skin sensitization.
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Electrical Safety: Requirements for medical electrical equipment used in the home – IEC 60601-1

EMC: Requirements for Electromagnetic Compatibility of Medical Equipment – IEC 60601-1-2

Software: Moderate Level of Concern - Documents and testing provided according to FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

Performance Bench Testing: Bench testing to validate the technical specifications and functionality of the device, including the vibratory and ultrasonic frequencies as well as duty cycles.

Shelf Life: Durability testing to demonstrate that the subject device maintains acceptable performance throughout the use life proposed in the labeling.

CLINICAL DATA:

The following data was submitted to demonstrate substantial equivalence in labeling:

A prospective 30 days, non-randomized, blinded, single-center clinical study was performed. The study had nineteen (N=19) male and female patients, ranging in age from 23 to 49 years, who all completed the study using the Klinly Ultrasonic Tongue Cleaner.

The study evaluated the changes in Breath Malodor, Tongue Plaque, and Tongue Bacteria Counts between the baseline and the 30 days endpoint of the study, demonstrating:

- Breath Malodor reduction of 37% at $p=0.0002$
- Tongue Plaque reduction of 41% at $p<0.0001$
- Tongue Bacterial Count reduction of 75% at $p=0.0401$

There were no protocol deviations and no adverse events.

CONCLUSION:

Based on the the information presented above, the Klinly Ultrasonic Tongue Cleaner demonstrates substantial equivalence to the Primary Predicate and Reference Devices.