Jeffrey Ward Cash, DDS
10149 Bon Air Crest Drive
North Chesterfield, Virginia 23235-4868

July 27, 2018

Re: K173808
Trade/Device Name: Voutia™
Regulatory Class: Unclassified
Product Code: LFD
Dated: June 27, 2018
Received: June 27, 2018

Dear Dr. Cash:

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,

Mary S. Runner -S

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)*
K173808

Device Name
Voutia™

Indications for Use *(Describe)*
The Voutia™ system is indicated to provide relief of dry mouth by coating, moistening, and lubricating oral structures thereby relieving the symptoms of 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Virginia Head and Neck Therapeutics, LLC

510(k) Summary for K173808

Date Prepared	**06/27/2018**
Submitter	**Jeffrey Ward Cash, DDS, FICD**
Primary Contact	**Jeffrey Ward Cash, DDS, FICD** **10149 Bon Air Crest Drive** **North Chesterfield, VA 23235-4868**
Device Common Name	**Saliva, Artificial**
Trade Name	**Voutia™**
Product Code and Classification	**LFD, Unclassified**
Predicate Device	**Xeros Dry Mouth Pump Lorin Technologies Corporation K110116**
Device Description	Voutia™ is a non-sterile, single person use device for the treatment of xerostomia, consisting of a circuit board controlled pump, a fluid reservoir bottle, and tubing extension that goes from the pump, over a person's ear and transitions to a smaller tube that terminates in the user's oral cavity. The Voutia™ system delivers potable water to the mouth at nine (9) preprogrammed user selectable rates over a defined time, allowing stationary or portable hands free use.
Intended Use	The Voutia™ system is indicated to provide relief of dry mouth by coating, moistening and lubricating oral structures thereby relieving the symptoms of xerostomia (dry mouth).

Technological Characteristics	Device	Voutia K173808	Xeros-1 K110116
	Intended use	Systematic Treatment of Xerostomia	Systematic Treatment of Xerostomia
	Method of use	Ready to use Liquid	Ready to use Liquid
	Applications per day	Use as needed	Use as needed
	Disease state	Xerostomia	Xerostomia
	Area of use	Oral Cavity	Oral Cavity
	Dispensed	Positive Displacement Pump	Positive Displacement Pump
	Presentation	Non-Sterile	Non-Sterile

Performance Testing	**<u>Non – Clinical Performance testing</u>** - Bench testing was conducted to confirm reproducibility of the water flow rate as intended on each selected level, meeting the predetermined internal testing criteria. - Biocompatibility assessment of fluid path components **<u>Clinical Performance testing</u>** was performed using a volunteer beta testing population who utilized the system during waking and sleeping hours to confirm proof of concept and functionality of the system. Evaluation of use was over a 16 month period and no adverse physiological events were reported by the participants.
Substantial Equivalence	Both devices utilize the same modality of fluid delivery (positive displacement pump) and both are controlled by a microprocessor driven pump delivering defined dose volumes. The submission device has reduced weight, visible profile and increased use between charges in comparison to the predicate device. The submission differs from the predicate with respect to 3 items: 1. The pumping system 2. the battery 3. polyimide microlumen tube. • Both submissions utilize a positive displacement pump. The submission incorporates the use of a piezoelectric diaphragm pump instead of the predicate's peristaltic pump. Both systems give the desired result while eliminating a transported fluid's contact with contaminants. The piezoelectric pump also been used in numerous medical and laboratory devices to date with a high degree of safety and success. • The lithium polymer battery has been tested by Underwriters Laboratory and passed all safety testing consistent with a single cell power source. Unlike the predicate device the submission's battery is housed in a protective urethane housing which sequesters it from inadvertent environmental damage. • The Polyimide tubing is routinely used in more invasive medical devices and procedures and meets USP Class VI testing evaluation. Consistent and historical biocompatibility has been established for this material.
Conclusion	The similarities in technology, intended use, and performance testing data provided for the Voutia system device support the conclusion that Voutia is substantially equivalent to the cited predicate device.