K110116

APR - 8 2011

Lorin Technologies Corporation

510(k) Notification
510(k) Submission

TRADITIONAL
Submission Date: 01/10/11

XEROS DRY MOUTH PUMP
artificial saliva

510(k) Summary
Submitted by

Owner's Name	Lorin Technologies Corporation
Address	436 Woodland Drive Swansboro, NC 28584-9418
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Contact Person	Vladimir "Al" Toman
Preparation Date	October 8, 2010

807.92(a)(1)

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510(k) Summary
Device Naming

Trade Name	XEROS Dry Mouth Pump XEROS-1	
Common Name	Artificial saliva	
Classification Name	Device	Saliva, Artificial
	Review Panel	Dental
	Product Code	LFD
	Unclassified Reason	Pre-Amendment
	Submission Type	510(k)
	Device Class	Unclassified
	TPLC	(see ref 1)
	GMP Exempt?	No
	Recognized Consenous Standard	(see ref 2) **Recognition Number 4-179: ISO 7405:2008, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry.** (Dental/ENT) Unclassified Saliva, Artificial Class U
	Third Party Review	Not Third Party Eligible

ref 1: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=1244
ref 2: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=26614
807.92(a)(2)

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510(k) Summary
Predicates

vicks powershot dry throat & mouth relief	the procter & gamble co.	K091419	08/28/2009
tgo spray	laboratoires carilene s.a.s.	K051812	10/21/2005

ref: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
807.92(a)(3)

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510(k) Summary
Description of the device as found in device labeling[1]

The XEROS Dry Mouth Pump is a microprocessor driven device which releases small amounts of water for a user-set duration at user-set intervals. It includes a rechargeable battery, water container, pump, and pump controller. The mouthpiece is a small comfortable fitting sponge attached to 1/8" tubing. All components of the XEROS Dry Mouth Pump are placed within a waist pack. It can be worn around the waist, on the shoulder, or placed on the nightstand for example.

How the device functions[1]

The vessel is filled with water. The device is turned on and either the Day Mode or Night Mode is selected. The sponge-tip foam mouthpiece is wetted and then placed into the user's mouth where it is most comfortable.

The device is completely programmable designed to best fit the activity in which the user is engaged. It will pump water for the number of seconds the user presets the duration in the desired mode (Day or Night). It will pump that same amount of water at the number of minutes the user presets the interval in the desired mode. The process will continue until the device is turned off.

The user can push the BOOST button at anytime it is needed to deliver a preset amount of water measured in duration of seconds or the BOOST button can be depressed to activate pumping until it is released.

Scientific concepts that form the basis for the device

The concept of the device is simply to get water from a vessel container into the oral cavity of the user hands-free. Radiation caretakers advise their patients to sip water whether it be straight or a saline solution[2] . Saliva is 99% water[3]. These two statements form the basis for the device. However because sipping water from a bottle is not feasible while sleeping, engaged in physical activity, or speaking, using scientific logic, we enhance this concept by making the sipping of water hands-free. A peristaltic pump is incorporated to *sip* the water from the bottle into the oral cavity by way of a conduit. Like the predicates the XEROS-1 uses a positive displacement pump. Unlike the predicates the XEROS-1 pump is motorized whereas the predicates rely on manual hand motion.

1- Proposed Labeling page 13.2
2- Nurse Ann, Craven Regional Medical Center RDO, 2000 Neuse Boulevard, New Bern, NC 28560
3- http://www.answers.com/topic/what-is-the-composition-of-saliva

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510(k) Summary
Significant physical and performance characteristics

The device is designed to be as compact and weight-light as possible. The device components are contained within a waist pack, each in their own compartment. The only requirement of the battery is that it must be rechargeable. At the present a gel cell is being used however as battery technology advances it will be replaced by a much lighter and less bulky (less physical mass) battery such as a lithium cell based battery. The water bottle container is polyethylene, same as the Vicks Power-shot predicate. The bottle being used is 6 ounces based on typical usage calculations and actual studies to verify those calculations. However, the bottle size can be up-sized or down-sized without adversely effecting the function of the XEROS-1. The pump is a peristaltic positive displacement pump chosen in design because the water does not come into direct contact with any of the pump components. The pump being low voltage makes it possible to be portable. Pump technology is advancing and a smaller pump profile is being considered which will not only be more electronically efficient it will be lighter in weight and size. The last component contained within the waist pack is the controller. It resides in a mesh outer pocket so that it is visible but yet obscure. With practice, the user can use the controller without actually looking at it. The buttons are designed to be operable by touch. Striking any of the buttons by mistake will neither cause harm to the user nor adversely effect the use of the XEROS Dry Mouth Pump. The controller contains two simple circuits 1) one to recharge the battery (and to shutdown if the battery is not recharged) and 2) one to program and operate the pump. The tubing from the discharge side of the pump and the removable foam sponge-tip mouthpiece assembly are the only components not in the waist pack during operation. The discharge tubing is Tygon® Medical/Surgical Tubing S-50-HL. The only component of the XEROS-1 that comes into contact with the oral cavity is the disposable foam sponge-tip mouthpiece assembly. It consists of the foam sponge-tip (toothette swab standard 10993-5 for the biological evaluation of medical devices), tubing (Tygon® Medical/Surgical Tubing S-50-HL), and female luer. The mouthpiece assembly is designed to be easily replaced by turning the luer a quarter turn and switching out mouthpieces.
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510(k) Summary
Intended Use

The XEROS Dry Mouth Pump is intended as dry mouth therapy for chronic dry mouth caused by radiation therapy treatment by adding moisture to the mouth for immediate and effective relief.

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510(k) Summary
Technological Characteristics

The XEROS Dry Mouth Pump device applies moisture to the mucus membrane of the mouth as a liquid by means of a positive displacement pump. By coating and moistening it treats dry mouth and provides immediate relief.

The XEROS-1 is in comparison with the predicates as shown in the table below.

	XEROS-1	Vicks Powershot	TGO Spray(R)
Intended Use	Symptomatic Treatment of xerostomia	Symptomatic Treatment of xerostomia	Symptomatic Treatment of xerostomia
Method of Use	Ready to use liquid	Ready to use liquid spray	Ready to use liquid spray
Applications per Day	As needed	As needed	As needed
Disease State	Xerostomia	Xerostomia	Xerostomia
Area of Use	Oral Cavity	Oral Cavity	Oral Cavity
Dispensed	Positive Displacement Pump	Positive Displacement Pump	Positive Displacement Pump
Presentation	Non-Sterile	Non-Sterile	Non-Sterile

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The data provided for XEROS Dry Mouth Pump device support the conclusion that it is substantially equivalent to the cited predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Al Toman
President
Lorin Technologies Corporation
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Swansboro, North Carolina 28584

APR - 8 2011

Re: K110116
Trade/Device Name: XEROS Dry Mouth Pump
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LFD
Dated: January 11, 2011
Received: January 14, 2011

Dear Mr. Toman:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Lorin Technologies Corporation

510(k) Notification
510(k) Submission

TRADITIONAL
Submission Date: 01/10/11

XEROS DRY MOUTH PUMP
artificial saliva

510(k) Number (if known): K110116

Device Name: XEROS Dry Mouth Pump

Indications for Use:
Dry mouth therapy for chronic dry mouth caused by radiation therapy treatment by adding moisture to the mouth for immediate and effective relief

Prescription Use __**NO**___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __**YES**___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110116

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