DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 18, 2016

LED Dental, Inc.
% Mr. Daniel Kamm
Principal Engineer
Kamm and Associates
8870 Ravello Court
NAPLES FL 34144

Re: K153710
Trade/Device Name: Tuxedo Digital Dental Sensor
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: February 24, 2016
Received: February 26, 2016

Dear Mr. Kamm:

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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153710

Device Name
Tuxedo Digital Dental Sensor

Indications for Use *(Describe)*
The Tuxedo Digital Dental Sensor is a CMOS sensor for the capturing of digital diagnostic x-ray images on a patient for evaluation by an appropriately trained oral healthcare professional. The Tuxedo sensor itself is a single piece comprised of the image capture components on one end, with a USB 2.0 plug on the other end. The sensor is designed to be used in conjunction with a disposable, single-use hygienic sheath as well as a positioning device to allow for proper alignment within the patient's mouth. Images are acquired with the Tuxedo sensor by plugging it into a USB port and properly placing it in the patient's mouth, while an operator exposes radiation toward the sensor from an approved intraoral x-ray generator.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: LED Dental INC.
Tuxedo Dental Digital Sensor

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

1. **General Information**

Business Name:	LED Dental INC
Address:	No. 235-5589 Byrne Rd. Burnaby, BC, CANADA V5J 3J1
Phone Number:	404-432-2819
Contact Person:	Wesley Newsom
Date of 510(k) Preparation:	November 23, 2015

2. **Device Name and Classification**

Proprietary-Trade Name: "Tuxedo Digital Dental Sensor"

Device:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
Regulation Description:	Stationary x-ray system
Regulation Medical Specialty:	Radiology
Review Panel:	Radiology
Regulatory Class:	Class II
Product Code:	MQB
Regulation Number	892.1680

3. **Equivalent legally marketed device: K143000**

Proprietary-Trade Name: RIO Sensor (RIS 500),

Device:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
Regulation Description:	Stationary x-ray system
Regulation Medical Specialty:	Radiology
Review Panel:	Radiology
Regulatory Class:	Class II
Product Code:	MQB
Regulation Number	892.1680

4. Indications **for Use:** The Tuxedo Digital Dental Sensor is a CMOS sensor for the capturing of digital diagnostic x-ray images on a patient for evaluation by an appropriately trained oral healthcare professional. The Tuxedo sensor itself is a single piece comprised of the image capture components on one end, with a USB 2.0 plug on the other end. The sensor is designed to be used in conjunction with a disposable, single-use hygienic sheath as well as a positioning device to allow for proper alignment within the patient's mouth. Images are acquired with the Tuxedo sensor by plugging it into a USB port and properly placing it in the patient's mouth, while an operator exposes radiation toward the sensor from an approved intraoral x-ray generator.

5. Device Description: The TUXEDO Dental Digital Sensor is used in the detection and diagnosis of anomalies in dental anatomy, as well as for the evaluation of performed treatment in dental care. The primary use is by general dental practitioners to detect the presence and extent of carious legions in the dentin and enamel of a tooth. Two different sized sensors (size 1 and size

2) are utilized to image different anatomy and different patient sizes. The TUXEDO Dental Digital Sensor functions by being placed in a patient's mouth lingually by a licensed dental practitioner, and is designed to capture collimated radiation which is converted into a digital image for viewing by a licensed dental practitioner. The capturing of the radiation is done within the TUXEDO sensor casing which contains a scintillator used to convert the radiation into visible light, and this visible light is immediately captured by the internal CMOS sensor. The digital image is transferred to a computer via USB 2.0 and can be viewed in most common imaging software programs, including LED Imaging Software. A software driver is available from LED Dental which will allow the TUXEDO sensor to be used in these software programs. The software supplied with the Tuxedo Digital Dental Sensor was cleared separately by FDA by Apteryx, Inc. The sensor is intended to be used with a disposable barrier sheath that should be replaced between patients. This is to reduce cross contamination between patients. The sensor is also sealed in a way that the portion of the device that is placed in the patient's mouth can be sterilized with liquid without the device being damaged.

6. Substantial Equivalence

Comparable Properties	RIO Sensor (RIS 500), K143000	"Tuxedo Digital Dental Sensor"	Comparison Results
Indications for Use	This system is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, views and manipulated for diagnostic use by dentists.	The Tuxedo Digital Dental Sensor is a CMOS sensor for the capturing of digital diagnostic x-ray images on a patient for evaluation by an appropriately trained oral healthcare professional. The Tuxedo sensor itself is a single piece comprised of the image capture components on one end, with a USB 2.0 plug on the other end. The sensor is designed to be used in conjunction with a disposable, single-use hygienic sheath as well as a positioning device to allow for proper alignment within the patient's mouth. Images are acquired with the Tuxedo sensor by plugging it into a USB port and properly placing it in the patient's mouth, while an operator exposes radiation toward the sensor from an approved intraoral x-ray generator.	These statements are functionally equivalent
Computer Interface	USB 2	USB 2	Identical
Sizes	Size 1: 39x25 Size 2: 42x30	Size 1 39 x 25 mm Size 2 41.9 x 30.4 mm	Identical. Predicate rounded off the numbers
Sensor Thickness	5.6 mm	5.3 ± 0.3 mm	Essentially identical
Imaging Technology	CMOS	CMOS	Identical

Comparable Properties	RIO Sensor (RIS 500), K143000	"Tuxedo Digital Dental Sensor"	Comparison Results
Pixel Size	20.0 µm	20.0 µm	Identical
Scintillator Technology	Csl Scintillator	Csl Scintillator	Identical
Image Sizes	Size 1: 1000x1500 pixel Size 2: 1300x1700 pixel	1000 x 1500 pixels 1300 x 1700 pixels	Identical
Theoretical Resolution	25 lp/mm	25 lp/mm	Identical
MTF	More than 30% at 6 lp/mm	More than 30% at 6 lp/mm	Identical
DQE	More than 40% at 2.5 lp/mm	More than 40% at 2.5 lp/mm	Identical
Computer	Not specified	PC or Tablet with Windows Vista® SP2 or above, Windows® 7, Windows® 8, Windows Server® 2003 R2, Windows Server® 2008, and Windows Server® 2012 operating systems including Terminal Services and Citrix®. The software has been cleared by FDA in a separate submission. (Apteryx, Inc, K983111)	New device covers a wider range of operating systems
Infection control	Requires a single patient use FDA cleared hygienic barrier	Requires a single patient use FDA cleared hygienic barrier, for example TIDIShield™ K132953. Sheaths: Code # 21041 for Size 1 Code # 21040 for Size 2	Identical
Photo			The same sensor is being used by the predicate.

7. **Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:** The comparison results show essentially identical characteristics or negligible differences. We conclude that our Tuxedo device is substantially equivalent in terms of safety and effectiveness**.** Looking at the photo and the specification comparisons, it appears that the predicate is using the same exact sensor as ours.

8. **Performance Testing:** Successful standards testing was done according to the following:
   Radiated Emission IEC60601-1-2: 2007, including Radiated Immunity EN61000-4-3, and Electrostatic Discharge (ESD) EN61000-4-2.
   Dielectric strength and PATIENT LEAKAGE CURRENT and Temperature of APPLIED PARTS: IEC60601-1:2005.
   Imaging performance tests were conducted according to IEC62220-1, Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency.
   Other testing: The stability of sensitivity, dark output and offset value.
   Mechanical Strength Testing: Bending and Pulling Test of Cable
   Other Reliability Test Reporting: Dropping, Alcohol Dipping, Air leakage, Mechanical Strength of APPLIED PART, and Transport testing.
   Although the device does not directly contact the patient, biomedical conformity was evaluated according to food utensil safety requirements of Japan.
   We also conducted a risk analysis according to the recommendations of IEC 14971, Application of Risk Management to Medical Devices. There are three broad categories of risk: Broadly Acceptable Region; Marginal; countermeasure required to reduce risk to acceptable level (ALARP) and Intolerable; countermeasure required to reduce risk to acceptable level. After applying countermeasures, all risks were reduced to the BA (broadly acceptable) category. The application of the standards testing (above) was the main method of risk reduction, as well as relying on the use of FDA cleared components such as the sanitary barriers and the software. The sensor has been previously cleared as well.

9. **Clinical Testing:** Clinical images were provided using a Phantom equivalent to a 51 year old male. Phantom Utilized for Image Capture:
   DXTTR III Dental X-Ray Phantom (Human Skull): A training phantom. With real skull and teeth with silicone face etc.
   Intra-Oral X-Ray Generator Utilized: Gendex Expert DC
   These images were not necessary to establish substantial equivalence based on the modifications to the device (note CMOS detector that is very similar to the predicate dental detector Rio), but they provide further evidence in addition to the laboratory performance data to show that the complete system works as intended. All images acquired demonstrated excellent diagnostic imaging quality on both the size #1 and the size #2 sensor. The sensors demonstrated a good latitude response from variations in generator settings. Contrast and spatial resolution on all images were good to excellent on all images acquired.

10. **Conclusion as to Substantial Equivalence:** In accordance with the federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, LED Dental concludes that the Tuxedo Digital Dental Sensor is safe and effective to perform its intended use as well as substantially equivalent to the predicate device.