October 20, 2023

Tuxedo Imaging LLC
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

Re: K232552
Trade/Device Name: Tuxdeluxe (Size 1 6100B, Size 2 6101B)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: August 20, 2023
Received: August 23, 2023

Dear Mr. Daniel 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. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232552

Device Name
Tuxdeluxe (Size 1 6100B, Size 2 6101B)

Indications for Use *(Describe)*
Dental Sensors, models Tuxdeluxe, 6100B-Size 1, and 6101B-Size 2 are intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists. This device must only be used in hospital environments, clinics or dental offices by trained and qualified dental personnel, and not used in the oxygen rich environment. This device is suitable for providing dental radiography imaging for both adult and pediatric patients.

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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510(k) Summary K232552
Tux Deluxe Intraoral Dental Digital Imaging Sensors

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 872.1800. Date prepared: September 18, 2023

1. **Company and Correspondent making the submission:**
   Tuxedo Imaging, LLC
   313 S. High Street**,** Suite 200
   Akron, OH 44308
   Contact: Patrick Williams, President, Tel 330 382-5733

2. **Trade /Proprietary Names: Tuxdeluxe (Size 1 6100B, Size 2 6101B)**
   Regulation Number: 21 CFR 872.1800
   Regulation Name: Extraoral source x-ray system
   Regulatory Class: Class II
   Product Code: MUH

3. **Legally Marketed Predicate Device Information: K220422**
   Manufacturer: iRay Technology Taicang Ltd.
   Trade/Device Name: Dental Sensors NanoPix1, NanoPix2
   Regulation Number: 21 CFR 872.1800
   Regulation Name: Extraoral source x-ray system
   Regulatory Class: Class II
   Product Code: MUH

4. **Description:**
   This Intraoral Dental Digital Imaging Sensor employs CMOS (Complementary Metal-Oxide-Semiconductor), protective optical fiber and scintillator. This sensor was developed to obtain a high-quality x-ray image from the human mouth and its structures. The acquisition process is made by positioning the sensor inside the mouth, behind the structure you want to perform the exam. The structure must be exposed to an x-ray dose using an external source. Once exposed, the sensor performs a conversion of the x-ray photons into a digital signal and transfers it to a computer through USB connection (Universal Serial Bus). The x-ray generator (an integral part of a complete dental x-ray system) is not part of the device. Device sensor sizes:
   Size 1: 24.1 x 36.2 x 5.9mm
   Size 2: 30.5 x 42.8 x 5.7mm
   The I/O sensor is compatible with the following cleared software: Xray Vision / XV Capture (XV Web) / Curve / Sota. This software must be purchased separately by the end user.

5. **Indications for use:**
   Dental Sensors, models Tuxdeluxe, 6100B-Size 1, and 6101B-Size 2 are intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists. This device must only be used in hospital environments, clinics or dental offices by trained and qualified dental personnel, and not used in the oxygen rich environment. This device is suitable for providing dental radiography imaging for both adult and pediatric patients

6. **Comparison with predicate device:**
The new devices Tuxdeluxe Sensors (and its predicate) are small digital imaging receptors that may be used in place of dental x-ray film.
Predicate sensor sizes:
Size 1: 25 x 38.5 mm ,
Size 2: 31 x 40 mm
Subject device sensor sizes:
Size 1: 24.1 x 36.2 mm
Size 2: 30.5 x 42.8. mm

The images are displayed on a computer workstation. The technologies employed by the predicate and our new device are almost identical. The proposed sensors have greater resolution than the predicate via smaller pixel size and greater numbers of total pixels. The same sensor sizes are available, and the computer interface is the same (USB). Both sensors use CMOS technology. Similarities: Indications for Use, available sizes, USB interface, CMOS technology employed. Differences: New device has greater resolution via smaller pixel size and greater number of pixels. The sensor sizes are nearly identical.
A comparison table follows:

PRODUCT	K220422 Trade/Device Name: Dental Sensors NanoPix1, NanoPix2	Tuxdeluxe Intraoral Dental Digital Imaging Sensor
Indications for use	Dental Sensors, models NanoPix1 and NanoPix2 are intended to collect dental xray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists. This device must only be used in hospital environments, clinics or dental offices by trained and qualified dental personnel, and not used in the oxygenrich environment. This device is suitable for providing dental radiography imaging for both adult and pediatric.	Dental Sensors, models Tuxdeluxe, 6100B-Size 1, and 6101B-Size 2 are intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists. This device must only be used in hospital environments, clinics or dental offices by trained and qualified dental personnel, and not used in the oxygenrich environment. This device is suitable for providing dental radiography imaging for both adult and pediatric patients. SAME
Where Used	Clinics, hospitals, dental offices	SAME
Operating Temperature Range	10˚C to 30˚C	+5°C to +35°C Greater operating temperature range.
Supply Voltage	+5 Vdc (USB)	+5 Vdc (USB)
Technology	CMOS	CMOS
Contrast	12 bits	12 bits
Gray Level	4096	4096
Pixel Size	20 µm	14 µm
Number of pixels	Size 1 1000 x 1500 Size 2 1300 x 1800	Size 1: 1404 x 2104 pixels Size 2: 1852 x 2574 pixels
Line pairs/mm	16 Line pairs/mm	35 Line pairs/mm
MTF	0.1 at 12.5lp/mm	0.095 at 12.5lp/mm (Essentially the same)

PRODUCT	K220422 Trade/Device Name: Dental Sensors NanoPix1, NanoPix2	Tuxdeluxe Intraoral Dental Digital Imaging Sensor
DQE	DQE @ RQA5: >61.3% @ 0 lp/mm	DQE @ RQA5: >65% @ 0 lp/mm
Active Sensor Area	Size 1: 25 x 38.5 mm , Size 2: 31 x 40 mm	Size 1: 24.1 x 36.2 mm Size 2: 30.5 x 42.8. mm SIMILAR
Imaging Software	NanoPix included	Not included. Compatibility verified with these previously cleared software packages: XrayVision K983111 XVCapture/XVWeb K983111 Curve K110139 Sota K210682
Target Computer System Type	Windows with USB	SAME
Connection type	USB 2 or 3	SAME
Cable Length	10 ft.	2 or 3 m (6 ft or 9 ft) SIMILAR
Patient Protection	Single Use Patient Protective Barrier, FDA ckeared	Single Use Patient Protective Barrier, FDA ckeared SAME
Photo		

7. **Non-clinical Testing Performed: Safety, EMC, Biocompatibility and Performance Data:**
   Safety testing: Electrical, mechanical, environmental safety and performance testing according to standards:

   SAFETY TEST ACCORDING TO THE STANDARDS IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint) and EN 60601-1:2006+ A1:2013 + A12:2014, Recognition #19-49
   ELECTROMAGNETIC COMPATIBILITY TESTS according to the standards: IEC 60601-1-2 Ed4.0 (2014) EN 60601-1-2 Ed4.0 (2015) Recognition 19-36 with a declaration of conformity to IEC TR 60601-4-2 Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems Recognition 19-19.
   USABILITY ACCORDING TO THE STANDARDS IEC 60601-1-6:2010 (Third Edition) + A1:2013 and EN 60601-1-6:2010 +A1:2015 Recognition 5-89

Verification of degrees of protection IP68 provided by the enclosure according to the standards IEC 60529: 2013 and NF EN 60529: 1992 + A1: 2000 + A2: 2014

The main patient contact material is the FDA cleared barrier sheath (K160232, Disposable Barrier Sleeves and Covers), not supplied by us.

Successful operation has been demonstrated with these previously cleared dental imaging software packages:
XrayVision K983111
XVCapture/XVWeb K983111
Curve K110139
Sota K210682
The user must purchase one of these software programs separately.

Risk analysis was conducted. All test results were satisfactory. Cybersecurity concerns were addressed via labeling. Reference: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*. We also had an image quality analysis performed by a USA Board Certified Dentist who reviewed the proposed device images. He concluded that the images are of good quality, clinically acceptable, and suitable for the intended use.

8. **Clinical Testing Performed: Clinical testing is not required for a finding of substantial equivalence.**

9. **Conclusions:** Our conclusions drawn from the nonclinical tests (discussed above) are that we have demonstrated that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device identified according to 807.92(b)(3), 57 FR 18066, Apr. 28, 1992, as amended at 59 FR 64295, Dec. 14, 1994, According to the Federal Food, Drug and Cosmetic Law, 21 CFR Part 872. Based on the information provided in this pre-marketing notification, Tuxedo Imaging, LLC concludes that Intraoral Dental Digital Imaging Sensor is safe and effective and substantially equivalent to predicated devices, as described in this document.