July 20, 2018

Sodium Systems, LLC
% Brandon Bachler, Ph.D.
Chief Technology Officer
1050 Highland Drive, Suite E
ANN ARBOR MI 48108

Re: K181636
Trade/Device Name: Aurora
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: June 18, 2018
Received: June 21, 2018

Dear Dr. Bachler:

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.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181636

Device Name
Aurora

Indications for Use *(Describe)*
Aurora is an intra-oral sensor used by dental professionals for the purpose of acquiring x-ray images to be used for the diagnosis of diseases of the mouth and for evaluating general dental health.

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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510(k) Summary

Submitter

Sodium Systems, LLC
1050 Highland Drive, Ste. E
Ann Arbor, MI 48108
Date: 6/5/2018

Phone: 800-821-8962
Fax: 866-611-0677
Contact Person: Brandon Bachler
Contact email: brandon.bachler@sodiumdental.com

Device Name/Classification

Proprietary trade name: Aurora
Common name: Intraoral digital x-ray sensor
Classification name: Extraoral Source X-ray System
Regulatory class: Class II
Regulation number: 21 CFR 872.1800
Classification Code: MUH
Submission type: 510(k) - Traditional
Medical Specialty: Dental

Predicate Device

Company: Denterprise International, Inc.
Device name: QuickRay HD
510(k) number: K151926
Regulation number: 21 CFR 872.1800
Regulation name: Extraoral source x-ray system
Regulatory class: II
Classification code: MUH
Clearance date: December 14, 2015

Product Description

Aurora is an intraoral digital x-ray system used to acquire digital x-ray images when used with an external x-ray source.

The sensor is composed of a scintillation plate that converts incident x-ray light into visible light, which is coupled to a CMOS detector via a fiber optic plate (FOP) collimator. It connects to a PC via a 2-meter cable with USB 2.0 interface. A trained dental professional (e.g. Dentist, Dental Assistant, etc.) will operate the sensor by aligning the device inside the mouth using a positioning device, such as ring and bar holder, and then using an external x-ray source (i.e. dental x-ray tube head) to expose the sensor to radiation with the oral tissue of interest between.

A software package will control the acquisition of the x-ray image from the sensor itself and will interpret the data to create an image on a computer screen for the dentist to use for diagnosis. Neither the software package nor the x-ray sensor controls the x-ray generating source in any fashion. The software package used by Sodium Dental is Xray Vision® from Apteryx, Inc (K983111). The Xray Vision® software is a network-based image acquisition and management software used to acquire x-ray/camera images and store them in a patient database.

Aurora is designed to be used at all times with a sensor barrier to prevent any direct contact with the inside of a patient's mouth, an example of which is the product from Trollhatteplast AB.: TrollBag – registration number 3004116514. When used properly with a new sensor barrier for each patient, the unit can be reused without the need to use sterilization equipment that would destroy the sensor. At no point does the sensor itself come in contact with the patient's mouth. Sodium Systems provides thorough instructions for handling and cleaning the sensor.

Indications for use

Aurora is an intra-oral x-ray sensor used by dental professionals for the purpose of acquiring x-ray images to be used for the diagnosis of diseases of the mouth and for evaluating general dental health.

Intended use

The Aurora sensor is recommended for use with a ring and bar style holder for alignment, although the use of such a device is not critical to the function of the sensor. The sensor comes in two sizes, Size 1 and Size 2, designed to accommodate the acquisition of images in different locations (e.g. horizontal bite wings, vertical bite wings, anterior periapical, etc.) and different patient mouth sizes.

Comparison with Predicate Device

Aurora is an identical device to the predicate device, the QuickRay HD (K151926) by Denterprise International, Inc. The predicate device is the same hardware device from the same hardware manufacturer, Hamamatsu. The device differs from Aurora by labeling only – no functional differences between the predicate sensor and Aurora exist.

As with our device, the predicate device comes in two sizes, size 1 and size 2. In each case, the manufacturing number from Hamamatsu is identical.

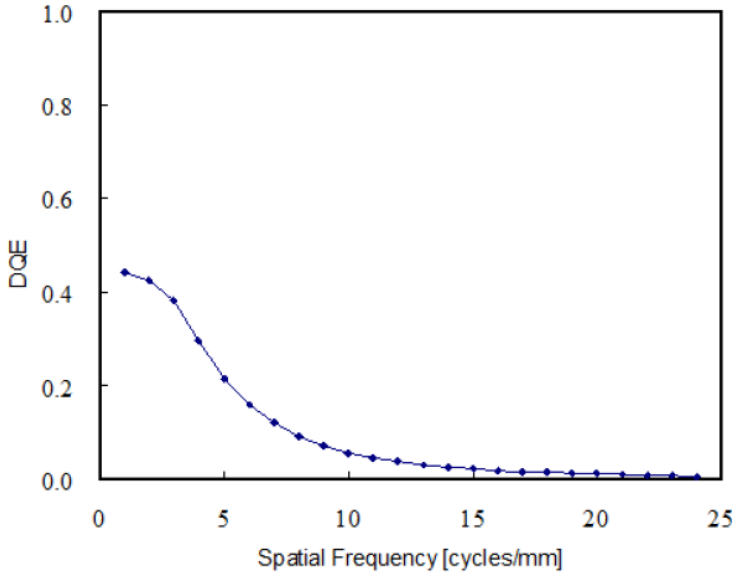
A comparison table between our sensor and the predicate device is provided below, although it should be noted that since it is identical hardware from the same manufacturer, all values in the table are necessarily the same. All values provided are for size 2 sensors. Size 1 devices are also identical to all predicate values.

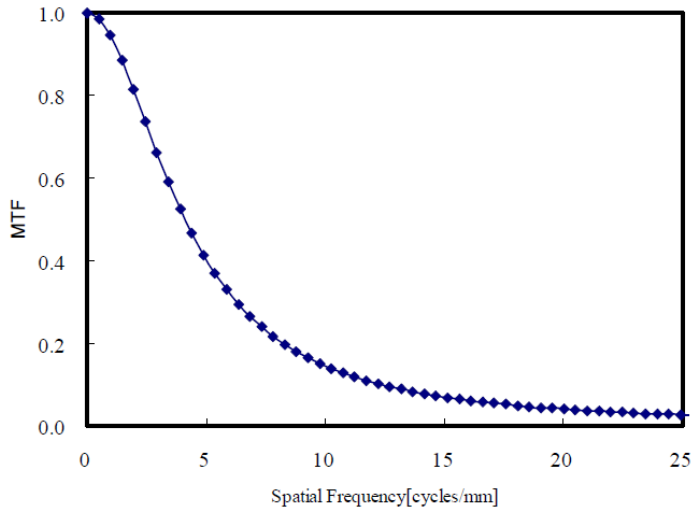
	Aurora sensor (subject)	**QuickRay HD (predicate)**	**Differences**
510(k)	Not assigned yet	K151926	N/A
Applicant/510(k) owner	Sodium Systems, LLC.	Denterprise International, Inc.	N/A
Manufacturer – Software Component	Apteryx, Inc.	Apteryx, Inc.	None
Classification & Product Code	872.1800; MUH	872.1800; MUH	None
Common Name	Intraoral Digital X-ray Sensor	Intraoral Digital X-ray Sensor	None
Indications for use	Acquisition of x-ray images to be used for the diagnosis of diseases of the mouth and for evaluating general dental health.	Radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structure.	Equivalent
Principles of Operation	X-ray (radiation) → scintillator (convert to visible light) → fiber optic plate (filtering) → CMOS (convert to digital image) → electronics → PC (capture and display image)	X-ray (radiation) → scintillator (convert to visible light) → fiber optic plate (filtering) → CMOS (convert to digital image) → electronics → PC (capture and display image)	None
Software – Firmware	Firmware combined on sensor electronic board	Firmware combined on sensor electronic board	None

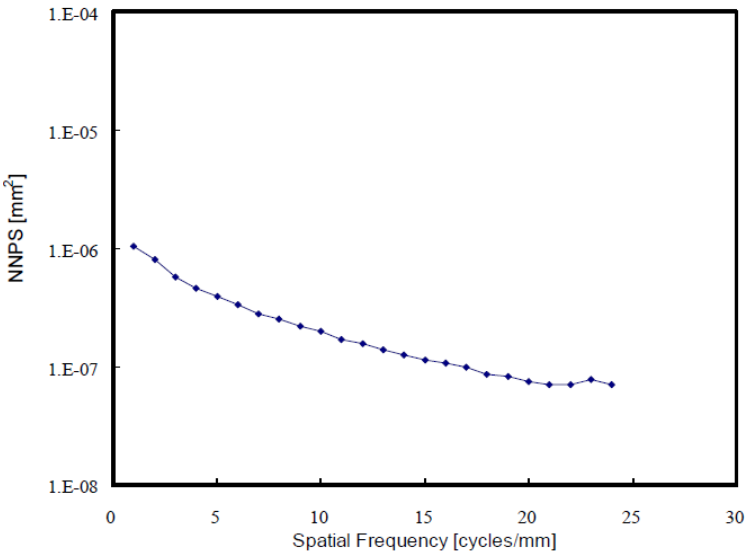
Software – Image Management	XRayVision (Apteryx, Inc.)	XRayVision (Apteryx, Inc.)	None
Sensor Technology	CMOS chip + fiber optic plate + CsI scintillator	CMOS chip + fiber optic plate + CsI scintillator	None
Matrix Dimensions (mm^2)	Active area: 600 mm^2 (Size 1); 884 mm^2 (Size 2)	Active area: 600 mm^2 (Size 1); 884 mm^2 (Size 2)	None
Matrix Dimensions (pixels)	1000 lines x 1500 lines (Size 1); 1300 lines x 1700 lines (Size 2)	1000 lines x 1500 lines (Size 1); 1300 lines x 1700 lines (Size 2)	None
CMOS Lifespan	Min. 100,000 cycles	Min. 100,000 cycles	None
Resolution	Real ≥ 20 lp/mm	Real ≥ 20 lp/mm	None
Pixel Size	20 x 20 µm	20 x 20 µm	None
Grey Levels	14 bits	14 bits	None
Sensor Board	All control electronics integrated directly on CMOS sensor chip	All control electronics integrated directly on CMOS sensor chip	None
Sensor Shell	Material is ABS and the flammability is HB if YK-94 (UL File No. 49895)	Material is ABS and the flammability is HB if YK-94 (UL File No. 49895)	None
Cable Material and Design	Cable consists of PVC, ETFE, copper, plug connector and sensor connector, diameter ϕ 3.7 ± 0.3 mm and cable length 2 meters.	Cable consists of PVC, ETFE, copper, plug connector and sensor connector, diameter ϕ 3.7 ± 0.3 mm and cable length 2 meters.	None
Connection to Imaging Practice PC	USB 2.0 High-speed	USB 2.0 High-speed	None
Operating Temperature	0° C to 35° C	0° C to 35° C	None
Sensor Input Voltage and Current	5V (via USB connection); 0.15 A Max	5V (via USB connection); 0.15 A Max	None
Standards of Conformity	IEC 60601-1 (Electrical) IEC 60601-1-2 (EMC) 62220-1 (Performance) 60529 (IP Code)	IEC 60601-1 (Electrical) IEC 60601-1-2 (EMC) 62220-1 (Performance) 60529 (IP Code)	None

Input	Calculation software*1	Output
MTF NNPS Φ	→ $DQE = \frac{MTF^2}{\Phi \cdot NNPS}$ →	DQE

*1: The calculation procedure is the same as that in IEC62220-1.







Performance Data

Clinical images were provided; these images were not necessary to establish substantial equivalence based on the modifications to the predicate device but they provide further evidence in addition to bench testing data to show that the complete system works as intended.

Clinical images were examined by Dr. Tiffany Danyal, D.D.S., a qualified practitioner of Clarkson Village Dental, Clarkston, MI. The images were determined by Dr. Danyal to be of diagnostic quality and usefulness for evaluation of all relevant oral structures.

Biocompatibility

Because Aurora is intended to be used with a sensor barrier shield, such as the product from Dentsply, Inc.: Universal Digital Sensor Cover (SKU 550500), there is no contact between the sensor and patient. As a result, biocompatibility testing is not necessary or pertinent for this device. Nonetheless, a biomedical conformity test report is included in this submission.

Electromagnetic Compatibility and Electrical, Mechanical, and Thermal Safety

Aurora has been tested for full compliance to electrical and safety standard **IEC 60601-1** - *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*, just as the predicate device has. Similarly, Aurora has been tested for full compliance to electrical and safety standard **IEC 60601-1-2** - *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility*.

Guidance Documents

The following device specific guidance documents were used in the development of the Aurora sensor:

1. *Guidance for the Submission of 510(k)s for Solid State Imaging Devices*, issued on September 1, 2016
2. *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued on May 11, 2005
3. *Pediatric Information for X-ray Imaging Device Premarket Notifications*, issued November 28, 2017
4. *Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, issued on October 2, 2014

Software Verification and Validation Testing

The Aurora sensor contains firmware and driver software, both provided by Hamamatsu. The Aurora sensor also uses imaging software - previously cleared by the FDA - provided by Apteryx, Inc. (Xray Vision®, K983111). Firmware and driver documentation for the subject device are included in this petition, along with the 510(k) summary for the Apteryx Xray Vision® companion software. Firmware and driver software were both cleared previously with the predicate device. **The previously cleared Apteryx XRay Vision Imaging Software has not been modified for use with Aurora.**

Bench Testing

Bench tests were performed on the Aurora, in accordance with IEC 60601-1 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance), IEC 60601-1-2 (Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests), IEC 62220-1 (Medical Electrical Equipment – Characteristics of Digital X-ray Imaging Devices – Part 1: Determination of the Detective Quantum Efficiency) and IEC 60529 (Degrees of Protection Provided by Enclosures – IP Codes).

Conclusion

Aurora is a sensor which **is identical in hardware and uses identical software to the predicate device**. The only differences between our device and the predicate device are marketing in nature – the name of the sensor and branding. No new technology, safety risks, or software are introduced in our device. Therefore, we feel that the device is substantially equivalent to the predicate device.