CND Global Technologies, Inc.
% Ms. Lisa Jager
Regulatory Affairs Consultant
Regulatory Science Solutions LLC
11576 W. M179 Hwy
MIDDLEVILLE MI 49333

March 1, 2019

Re: K190234
Trade/Device Name: ODI HD Dental Sensor
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: February 1, 2019
Received: February 6, 2019

Dear Ms. Jager:

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,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

## 4. Indications for Use Statement

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)*

K190234

Device Name
ODI HD Dental Sensor

Indications for Use *(Describe)*
ODI HD Dental Sensor is intended to be used by dentists and other qualified professionals for providing diagnostic x-ray radiographs of dentition, jaws and other oral structures.

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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K190234

# 510(k) Summary


| | |
|---|---|
| **Submitted By:** | CND Global Technologies, Inc.<br>16 Branch Avenue<br>Cumberland, RI 02864<br>319-333-6767 |
| **Contact Person** | Lisa Jager<br>Regulatory Affairs Consultant<br>11576 W. M179 Hwy<br>Middleville, MI 49333<br>regulatorysciencesolutions@gmail.com<br>616-802-2364 |


| | |
|---|---|
| **Date of Summary Preparation** | January 30, 2019 |
| **Trade Name** | ODI HD Dental Sensors |
| **Submission Number** | K190234 |
| **Common Name** | Intraoral Digital x-ray Sensors |
| **Classification Name** | Extraoral source x-ray system |
| **Classification** | Class II per 21 CFR 872.1800 |
| **Product Code** | MUH |
| **Classification Panel** | Dental |

## Predicate Device Information

| | |
|---|---|
| **Submitted By:** | Masterlink LLC |
| **Trade Name** | Apex Dental Sensors |
| **Submission Number** | K163282 |
| **Common Name** | Intraoral Digital x-ray Sensors |
| **Classification Name** | Extraoral source x-ray system |
| **Classification** | Class II per 21 CFR 872.1800 |
| **Product Code** | MUH |
| **Classification Panel** | Dental |

## Device Description

The ODI HD Dental Sensors are electronic medical device used to acquire intra-oral radiographic images. The sensor can be operated by Radiologists, Dentists, Dental Assistants and other healthcare professionals, who are both trained and competent to take Dental X-ray radiographs. Intra-oral positioning of the sensor is accomplished by the use of dedicated intra-oral positioning devices that facilitate the accurate alignment of the x-ray beam. The sensor may also be aligned with the assistance of the patient. The ODI HD Dental Sensors is an indirect light converting digital x-ray detector. A scintillating device composed of Cesium Iodide (CsI) converts incident x-rays into visible light that is optically coupled to a light detection imager based on CMOS technology. The ODI HD Dental Sensors allow for automatic detection of such incident x-rays in order to generate data. Software interprets this data into images used for dental applications. The ODI HD Dental Sensors support USB 2.0 direct connectivity to personal computers and or laptops with dedicated electronics and a sensor software driver. The subject device does not control the generator; it is only a receiver. The X-ray system and the software used are not a part of this submission.

The following hardware and software requirements need to be taken into account to ensure successful integration of ODI HD Dental Sensors with the X-ray systems.

**Hardware requirements:**

The type of x-ray systems that integrate with the Apex Dental Sensors are wall-mounted x-ray generators (both AC and DC) with a tube current between 1 and 15 mA inclusive, and with a tube voltage between 50 and 100 kV inclusive, with in-built controls to set exposure parameters. Generators allow variable mA/kV to be selected, all will control the exposure time.

The subject device is only a receiver, and not a controller. The subject device and the software cannot act as the controller of an x-ray generator. X-ray generators are controlled by built-in controllers and are not part of the subject device.

Premium Plus Disposable Barrier Sleeve (K163447) - Premium Plus Disposable Barrier Sleeve is intended to be used as a disposable barrier sleeve for ODI HD Dental Sensors. The Premium Plus Disposable Barrier Sleeve is non-sterile and intended for single patient use only.

**Software requirements:**

The Apteryx XrayVision software needs assistance from a TWAIN driver to recognize X-ray images. The recommended requirements for PC hardware for the sensor and software combination would be:

- Processor: Intel core i5-250m 2.5GHz or Higher
- Memory: 4G or higher
- Hard disk: Above 20G, 60G recommended
- Interface: USB 2.0
- Display: Resolution 1024 × 758 (15") or above
- Operating System:
    - Microsoft Windows 10(64/32 bit)
    - Microsoft Windows 8.1(64-bit)
    - Microsoft Windows 8(64-bit)
    - Windows 7 SP1 32 and 64-bit
- The computer connected to system shall be in accordance with IEC 60950-1:2005

**Indications for Use**

ODI HD Dental Sensor is intended to be used by dentists and other qualified professionals for providing diagnostic x-ray radiographs of dentition, jaws and other oral structures.

**Technological Characteristics**

The ODI HD Dental Sensors (Subject Device) makes use of a Predicate Device, Apex Dental Sensors (K163282). The detectors in the ODI HD Dental Sensors are the same as the detectors in the predicate device. The subject device and the predicate device are identical and sourced from the same supplier Hamamatsu. The model numbers of the ODI HD Dental Sensors are:

S11684-12 is Size #1

S11685-12 is Size #2

| Attribute | Subject Device-<br>ODI HD Dental Sensors | Predicate Device-<br>Apex Dental Sensors (K163282) | Equivalence | Difference and Justification |
|---|---|---|---|---|
| **General** | | | | |
| **Manufacturer** | CND Global Technologies Inc. | Masterlink LLC | | |
| **Classification and Product Code** | Class II<br>21 CFR 872.1800<br>MUH | Class II<br>21 CFR 872.1800<br>MUH | Equivalent | No difference |
| **Common Name** | Intraoral Digital X-ray Sensors | Intraoral Digital X-ray Sensors | Equivalent | No difference |
| **Classification Name** | Extraoral source X-ray System | Extraoral source X-ray System | Equivalent | No difference |
| **Classification Panel** | Dental | Dental | Equivalent | No difference |
| **Intended Use** | Providing diagnostic x-ray radiographs of dentition, jaws and other oral structures. | Radiographic examination to assist with diagnosis of diseases of the teeth, jaw, and oral structure. | Equivalent | No difference |

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|---|---|---|---|---|
| **Indications for Use** | ODI HD Dental Sensors is intended to be used by dentists and other qualified professionals for providing diagnostic x-ray radiographs of dentition, jaws and other oral structures. | The Apex Dental Sensors is intended to be used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw and oral structures. | Equivalent | No difference |
| **Number of Sensors** | 2 | 2 | Equivalent | No difference |
| **Cable Length** | 2m | 2m | Equivalent | No difference |
| **Pixel Size** | 20 x 20μm | 20 x 20μm | Equivalent | No difference |
| **Resolution** | 20 Lp/mm typ (S11684-12) | 20 Lp/mm typ (S11684-12) | Equivalent | No difference |
| **Technology** | CMOS chip +optical fiber plate + CsI scintillator | CMOS chip +optical fiber plate + CsI Scintillator | Equivalent | No difference |
| **Matrix dimensions ($mm^2$)** | Sensor Active Area: 600$mm^2$ (Size 1) 884$mm^2$ (Size 2) | Sensor Active Area: 600$mm^2$ (Size 1) 884$mm^2$ (Size 2) | Equivalent | No difference |
| **Principles of Operation** | X-ray (radiation) => scintillator (convert to light) => fiber optic (filtering) => CMOS (convert to digital)=> electronics=> PC (capture & display image) | X-ray (radiation) => scintillator (convert to light) => fiber optic (filtering) => CMOS (convert to digital)=> electronics=> PC (capture & display image) | Equivalent | No difference |
| **Other Requirements** | | | | |
| **Recommended PC Requirements** | Processor: Intel core i5-250m 2.5GHz or Higher or above; Memory: Above 4G; Hard disk: Above 20G, Interface: USB 2.0; Display: Resolution 1024 × 768 (15") or above Operating System: Microsoft Windows 10(64/32 bit) Microsoft Windows 8.1(64-bit) Microsoft Windows 8(64-bit) Windows 7 SP1 32 and 64-bit The computer connected to system shall be in accordance with IEC 60950-1:2005. | Processor: Intel 1.2GHz chip or above; Memory: Above 1G; Hard disk: Above 40G; Interface: USB 2.0; Display: Resolution 1024 × 758 (15") or above Operating System: Windows XP The computer connected to system shall be in accordance with IEC 60950-1:2005. | Equivalent | The Processor, Memory, Hard Disk and Operating System requirements for supporting use of the subject and predicate device differ slightly but are found to be equivalent. The outside supporting PC requirements do not impact the devices intended use, technical requirements or safety requirements. No differences are noted for Display and Computer IEC requirements. |
| **Connection to Imaging Practice PC** | USB 2.0 Interface | USB 2.0 Interface | Equivalent | No difference |
| **Software-Image Management** | Apteryx XrayVision | Apteryx XrayVision | Equivalent | No difference |
| **Sensor Board** | All control electronics directly integrated on CMOS sensor chip | All control electronics directly integrated on CMOS sensor chip | Equivalent | No difference |
| **Sensor input voltage and current** | USB2.0 (5V, 4.25min) | USB2.0 (5V, 4.25min) | Equivalent | No difference |
| **Operating Temperature** | 0℃～+35℃ | 0℃～+35℃ | Equivalent | No difference |

| Electrical Safety | | | | |
|---|---|---|---|---|
| **Standards of Conformity** | IEC 60601-1 (Electrical)<br>IEC 60601-1-2 (EMC)<br>IEC 62220-1 (Performance)<br>IEC 60529 (Performance) | IEC 60601-1-1 (Electrical)<br>IEC 60601-1-2 (EMC)<br>62220-1 (Performance)<br>IEC 61326-1 (EMC)<br>IEC 60601-2-65 (Electrical) | Equivalent | Cited standards differ slightly, however the devices are still found to be equivalent as the main Electrical, EMC and Performance standards cited are the same. |

**Similarities**

- The ODI HD Dental Sensors and Predicate Device both are available in two sizes
- The interface to PC of both ODI HD Dental Sensors and the Predicate is USB
- Both ODI HD Dental Sensors and the Predicate Sensor use CMOS technology, the pixel size for both sensors is 20 x 20µm
- The Sensor Active Area for ODI HD Dental Sensors and Predicate Device is the same i.e., 600mm2 (Size 1) and 884mm2 (Size 2)
- The principles of operation of ODI HD Dental Sensors and Predicate Device is the same, i.e., X-ray (radiation)=> scintillator (convert to light) => fiber optic (filtering) => CMOS (convert to digital)=> electronics=> PC (capture & display image)
- The Software-Image Management of ODI HD Dental Sensors and Predicate Device is the same, i.e., Apteryx XrayVision which has been cleared by the FDA under (K983111)
- Both ODI HD Dental Sensors and Predicate Device have all control electronics directly integrated on CMOS sensor chip
- The sensor input voltage is 5V in both ODI HD Dental Sensors and Predicate Device
- The operating temperature of ODI HD Dental Sensors and Predicate Device is also comparable, i.e., 0°C~+35°C
- The ODI HD Dental Sensors and the Predicate Device are tested per IEC 60601-1-1 and 60601-1-2 for Electrical Safety and Electromagnetic compatibility
- The recommended PC requirements in ODI HD Dental Sensors and the Predicate Device is also comparable. The processor that is recommended for ODI HD Dental Sensors is Intel core i5-250m 2.5GHz or Higher, whereas the processor for the Predicate Device is Intel 1.2GHz chip or above
- The ODI HD Dental Sensors and the Predicate Device have the same sensor resolution
- The ODI HD Dental Sensors and the Predicate have the same cable lengths. The sensor cable length in ODI HD Dental Sensors is 2m and in Predicate Device is also 2m.
- The interface for ODI HD Dental Sensors requires USB 2.0, and the Predicate Device also utilizes USB 2.0.

**Performance Data**

The following Performance testing has been performed on the Subject Device in accordance with appropriate FDA guidance documents and relevant standards, to support the determination of substantial equivalence. The test data showed that the Subject device is safe and effective for its intended use.

- Electrical and safety requirements established in AAMI ES 60601-1:2005/(R) 2012
- Electromagnetic compatibility requirements in IEC 60601-1-2 – Edition 3-2007
- IEC 62220-1:2015 – Determination of the Detective Quantum Efficiency Detectors used in Radiographic Imaging
- IEC 60529:2001 – Degrees of Protection Provided by Enclosures (IP Code)
- The Subject Device is also in compliance with FDA guidance document – Guidance for the submission of 510(k)s for Solid State X-ray Imaging Devices

**Clinical Performance**

Clinical data is not needed to characterize performance and establish substantial equivalence. The non-clinical test data characterizes all performance aspects of the device based on well-established scientific and engineering principles. Clinical testing has not been conducted on the ODI HD Dental Sensors.

**Conclusion**

The ODI HD Dental Sensors are substantially equivalent to the Predicate, and do not raise any new or different questions of safety or effectiveness. The subject and the predicate devices are identical; the only difference exists in the trade names (for marketing purposes).