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

August 26, 2015

Edlen Imaging LLC
% Nick Radachi
General Manager
16441 North 91st Street
Suite 102
SCOTTSDALE, AZ 85250

Re: K150823
Trade/Device Name: EDLENi Intra-Oral Sensor
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: MUH
Dated: August 11, 2015
Received: August 13, 2015

Dear Nick Radachi,

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 A Ochs

Robert Ochs, Ph.D.
Acting 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)*
K150823

Device Name
EDLENi Intra-Oral Sensor

Indications for Use *(Describe)*
The EDLENi sensor is an intra-oral x-ray sensor driven via CMOS technology indicated for the acquirement of intra-oral dental radiographs and intended for dental patients. The EDLENi will be handled via qualified dental and healthcare professionals in order to perform basic dental intra-oral x-ray imaging procedures. The sensors will be used to provide intra-oral radiographic images that ultimately diagnose general dental complications or abnormalities. The EDLENi sensor can be used in combination with positioning devices to facilitate alignment with the x-ray beam, or it may be positioned manually.

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

510(k) Summary

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Submitter: Edlen Imaging LLC

16441 N 91st Street Suite 102
Scottsdale, Arizona USA 85260

Contact Person: Nick Radachi

480-452-2939

nick@edlenimaging.com

Date Prepared: March 24, 2015

Trade Name: EDLENi Intra-Oral Sensor

Common Name: Digital x-ray sensor

Classification Name: 872-1800 Extraoral source x-ray system

Class: II

Product Code: MUH

Predicate Devices: The EDLENi is compared with the following predicate devices:

- Edlen Imaging's Gemini-DUSB system
  - Classification Name: System, X-ray, Extraoral Source, Digital
  - 510K Number: K103290
  - Product Code: MUH
- Schick Technologies' CDR system
  - Classification Name: System, X-ray, Extraoral Source, Digital
  - 510K Number: K072134
  - Product Code: MUH

Product Description: The EDLENi sensor is an 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 EDLENi sensor 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 EDLENi allows for automatic detection of such incident x-rays in order to generate data. Software interprets this data into images used for dental applications. The EDLENi sensor supports USB 2.0 direct connectivity to personal computers and or laptops with dedicated electronics and a sensor software driver.

Indication for Use: The EDLENi sensor is an intra-oral x-ray sensor driven via CMOS technology indicated for the acquirement of intra-oral dental radiographs and intended for dental patients. The EDLENi will be handled via qualified dental and healthcare professionals in order to perform basic dental intra-oral x-ray imaging procedures. The sensors will be used to provide intra-oral radiographic images that ultimately diagnose general dental complications or abnormalities. The EDLENi sensor can be used in combination with positioning devices to facilitate alignment with the x-ray beam, or it may be positioned manually.

Rationale for Substantial Equivalence: The only modifications in the subject device compared to the predicate are the two new Hamamatsu CMOS sensors. The detectors compared to the predicate have the same detection material; the modification is the readout using CMOS instead of CCD.

Safety and Effectiveness Information: The device labeling contains operating instructions for safe and effective use of EDLENi. The software development for this device follows documented processes for software design, verification and validation testing. Final device validation and risk assessment has been conducted, to identify potential design hazards that could cause an error or injury based on the use of this device. Appropriate steps have been taken to control all identified risks. The device has been tested for compliance to IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

Add'l Statements: Performance testing data according to the Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices have been provided to demonstrate substantial equivalence. Clinical images were not provided; clinical images were not necessary to establish substantial equivalence based on the modifications of the device.

Conclusion: EDLENi performs the same functions in the same environment as the predicate devices. It shares the same technology as the predicate devices. It is based on well known technology. It is as safe and effective as the predicate devices. We believe it does not introduce any new safety risks and is substantially equivalent to the predicate devices.