PaloDEx Group Oy
℅ Anni Lundholm
Regulatory Manager
Nahkelantie 160
Tuusula 04300
FINLAND

December 19, 2017

Re: K173646
Trade/Device Name: FS Ergo
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: November 10, 2017
Received: November 27, 2017

Dear Anni Lundholm:

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.

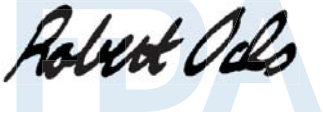
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173646

Device Name
FS Ergo

Indications for Use *(Describe)*

The FS Ergo sensor is a digital sensor which is indicated for acquiring dental intra-oral radiography images. The FS Ergo sensor shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intraoral radiographs.

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.

December 19, 2017

510(k) SUMMARY for FS Ergo

Submitter Information

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Device Name

Proprietary Name:	FS Ergo
Common Name:	Digital intraoral sensor system
Classification Name:	System, X-Ray, Extraoral source, Digital
FDA CDRH Panel:	Radiology
Product Code:	MUH
Regulation Number:	21 CFR 872.1800
Device Class: Class	II

Primary Predicate Device

Proprietary Name:	Snapshot
510(k) Number:	K081925
Manufacturer:	Instrumentarium Dental, PaloDEX Group Oy
Regulation Number:	21 CFR 872.1800
Regulation Name:	Extraoral source x-ray system
Product Code:	MUH
Device Class:	II

Reference Predicate Device

Proprietary Name:	EzSensor Soft (EzSensor Soft, EzSensor Soft i, EzSensor Bio, and EzSensor Bio I)
510(k) Number:	K151707
Manufacturer:	Rayence Co., Ltd.
Regulation Number:	21 CFR 872.1800
Regulation Name:	Extraoral source x-ray system
Product Code:	MUH
Device Class:	II

Description of the Device

The FS Ergo is a USB-driven sensor designed to capture intraoral digital dental x-ray images. FS Ergo can be used with any X-ray units intended for dental intraoral purposes. When connected to a computer with an appropriate image capturing software application, images are automatically acquired when the FS Ergo sensor receives a perceptible X-ray dose. The FS Ergo sensor is designed with advanced ergonomic principles. It has a bendable sensor housing together with other physical

features supporting advanced ergonomics: small diameter flexible cable, 32 degrees' cable exit and sensor dimensions that fit all needs (size 1.5). Comfort is achieved in with large corner chamfers, rounded edges, and thicker sensor structure.

The basic system of the FS Ergo consists of senor unit, sensor holders and hygienic covers (which are medical devices separately cleared by the FDA). A connection to a computer is required but the computer is provided by the users e.g. the computer is not part of the sensor system itself.

Indications for Use
The FS Ergo sensor is a digital sensor which is indicated for acquiring dental intra-oral radiography images. The FS Ergo sensor shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intraoral radiographs.

Description of Substantial Equivalence
The substantial equivalence of the FS Ergo is demonstrated by two predicate devices: primary predicate device Snapshot cleared under K081925 and manufactured by Instrumentarium Dental, Palodex Group Oy and secondary predicate device EzSensor Soft cleared under K151707 and manufactured by Rayence Co., Ltd. Indications for use of the FS Ergo and the predicate devices Snapshot (K081925) and EzSensor Soft (K151707) are not identical but they include the same fundamental elements of producing x-ray radiography images for professional use.

Snapshot (K081925) is the primary predicate device since its technological characteristics is most similar to the FS Ergo. EzSensor Soft (K151707) is the secondary predicate device since its structure (sensor head) is soft like the FS Ergo. EzSensor Soft is not, however, available for technical testing and image quality comparison.

Technical characteristics of the FS Ergo sensor and the predicate devices Snapshot cleared under K081925 and EzSensor Soft cleared under K151707 are described in the table 7-1 below.

Table 7-1. Significant characteristics comparison table.

Characteristics	**Primary Predicate Device Snapshot (K081925)**	**Secondary Predicate Device EzSensor Soft (K151707)**	**Subject Device FS Ergo**
Indications for Use	Snapshot is intended to be used by dentists and other qualified professional for producing diagnostic x-ray radiographs of definition, jaws and other oral structures.	EzSensor Soft, EzSensor Soft i, EzSensor Bio and EzSensor Bio i Digital Dental Intra Oral Sensors are intended to collect dental x-ray photons and convert them into electronic	The FS Ergo sensor is a digital sensor which is indicated for acquiring dental intra-oral radiography images. The FS Ergo sensor shall be operated by healthcare professionals, who

Characteristics	Primary Predicate Device Snapshot (K081925)	Secondary Predicate Device EzSensor Soft (K151707)	Subject Device FS Ergo
		impulses that may be stored, viewed and manipulated for diagnostic use by dentists.	are educated and competent to perform the acquisition of dental intraoral radiographs.
Sensor type	Intra-oral	Intra-oral	Intra-oral
Sensor Dimensions (mm)	Size 1: 37 x 26 Size 2: 42 x 31	Size 1.0: 38 x 27 Size 1.5: 41 x 31 Size 2.0: 44 x 33	Size 1.5: 40 x 30
Sensor Thickness (mm)	12	5.5	8.5
Sensor Shape	Rectangular, four rounded corners	Rectangular, four rounded corners	Rectangular, four rounded corners
Resolution – Pixel Size (µm)	19 x 19	14.8 x 14.8	17 x 17
Theoretical Resolution	26.3 lp/mm	33.78 lp/mm	29.4 lp/mm
Sensor Active Area (mm)	Size 1: 30 x 20 Size 2: 36 x 26	Size 1.0: 30 x 20 Size 1.5: 33 x 24 Size 2.0: 36 x 26	Size 1.5: 32 x 25
Sensor Housing	Rigid, polyamide (PA)	Soft, silicone with urethane coating	Soft, silicone with urethane coating
Connection to PC	USB 2.0	USB 2.0	USB 2.0
Electrical Rating	5 Vdc / 500 mA	5 Vdc / 500 mA	5 Vdc / 500 mA
IP Classification	Sensor: IP67	Sensor: IP68	Sensor: IP68
Mode of Operation	Continuous mode	Continuous mode	Continuous mode
Electrical Safety	IEC 60601-1:1998	IEC 60601-1:2015	IEC 60601-1:2015

Principle of Operation

The FS Ergo sensor is automatically powered when connected to the USB port on a workstation. No power switch is needed. User activates image capturing from an image capturing software installed on the connected workstation. The sensor detects x-ray exposure automatically and transfers the image to the software without additional user interaction. The FS Ergo can be used with any x-ray units intended for dental intraoral purposes in the range of 60 to 70 kV and at minimal 40 µGy incident dose.

After transmitting the image, the sensor is ready for the next exposure. A full mouth s series of image can be easily captured by sequentially activating the sensor from the software application. Image capture session can be terminated from the software application.

Non-Clinical Performance Data
The FS Ergo sensor has successfully passed internal design verification and validation.

Electrical, mechanical, safety and performance testing according to standards IEC 60601-1:2005, IEC 60601-1-6:2013, IEC 62366:2014 and IEC 62304:2006 were performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2:2014. Testing was completed by 3rd party test house, and the FS Ergo sensor has passed all tests.

Biocompatibility evaluation was conducted on patient contacting accessory parts and the materials. The parts are found to be in conformance with ISO 10993-1:2009.

Bench test images of skull phantoms were acquired using FS Ergo sensor, the images were reviewed by qualified external clinician to be of acceptable quality for the proposed intended use. Bench testing for the FS Ergo sensor was performed as recommended by the FDA's Guidance for the Submission of 510(k)s for Solid State X-Ray Imaging Devices. Bench testing results indicate substantial equivalence to the predicate device Snapshot.

Clinical Performance Data
Clinical data was not needed to support substantial equivalence.

Conclusion as to Substantial Equivalence
Based on the substantial equivalence comparison of intended use, design, technological characteristics, performance, labeling, biocompatibility, standards, and other characteristics, there are no significant differences found between the FS Ergo and the predicate devices Snapshot (cleared under K081925) and EzSensor Soft (cleared under K151707). Minor differences have not been shown to raise new concerns for the proposed indications for use.

The device does not introduce a fundamentally new scientific technology and the non-clinical tests demonstrate that the device is substantially equivalent to the predicate device. All internal verification and validation has been completed successfully.

In summary, FS Ergo sensor described in this submission is substantially equivalent to the Snapshot (cleared under K081925) and the EzSensor Soft (cleared under K151707) and satisfies all criteria of substantial equivalence.