DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 9, 2017

Jazz Imaging LLC
% W. Edward Johansen
Official Correspondent
395 14th Street, NE
SALEM OR 97301

Re: K163224
Trade/Device Name: JAZZ SOLO Sensor
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: February 17, 2017
Received: February 21, 2017

Dear Mr. Johansen:

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,

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

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)*
K163224

Device Name
JAZZ SOLO Sensor

Indications for Use *(Describe)*
The JAZZ SOLO digital sensor is intended to acquire dental intra-oral radiographic images. It can be operated by trained dental professionals for patients receiving intraoral x-ray examinations for diagnostic purposes.

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

Date Summary Prepared: March 6, 2017

Submitter Information

Name: Jazz Imaging LLC

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San Jose, CA 95131 USA

Contact Person: Todd C. Miller

Corporate Telephone: (650) 999-0909

Official Correspondent: W. Edward Johansen

Identification of Device

510(k) Number: K163224

Trade Name: JAZZ SOLO Digital Sensor

Common Name: Dental digital x-ray sensor

Classification Name: Extra-oral source x-ray system

Product Code: MUH

Class: II

Panel: Radiology

Regulation Number: 21 C.F.R. §872.1800

Equivalent legally Marketed Device (Predicate Device)

510(k) Number: K090458

Trade Name: DEXIS Sensor

Manufacturer: Sybron Dental Specialties, Inc.

Common Name: Dental digital x-ray sensor

Classification Name: Extraoral source x-ray system

Product Code: MUH

Classification: Class II

Panel: Radiology

Regulation Number: 21 C.F.R. § 872.1800

Device Description

The JAZZ SOLO Digital Sensor, Model 10-001, is a USB-driven digital sensor designed for health care professionals already acquainted with the standard procedures for acquiring dental intra-oral radiographs. Digital x-ray imaging is an aide for diagnosis and should always be confirmed by the doctor using additional procedures and other diagnostic aides for confirmation.

The JAZZ SOLO Digial Sensor is positioned in the patient's mouth in the same manner as intra-oral film is positioned.

The JAZZ SOLO Digital Sensor has an x-ray imager (CCD) that creates a digital image from x-ray doses perceptible by the sensor. The digital image created is immediately visible on the screen of a personal computer connected to the JAZZ SOLO Digital Sensor through the standard USB port. Image analysis software is not part of the submission. For the Jazz Solo Digital Sensor to be used in a dental practice, an optional image analysis software will be necessary. Only with image analysis software can acquired images be optimized for specific diagnostic tasks, archived as image files and printed out on a suitable printer.

The JAZZ SOLO Digital Sensor captures x-ray images suitable for recognition of normal anatomical structures, dental pathologies and abnormal conditions. Inadequate images may result in mis-diagnosis, subjecting the patient to incorrect or unnecessary dental procedures that would present an unacceptable risk to the patient.

Indications for Use

The JAZZ SOLO digital sensor is intended to acquire dental intra-oral radiographic images. It can be operated by trained dental professionals for patients receiving intraoral x-ray examinations for diagnostic purposes.

Intended Use

JAZZ SOLO Digital Sensor is intended for any dental practice that uses X-ray equipment for intraoral diagnostic purposes. It can be used by trained dental professionals for patients receiving intraoral X-ray examinations and produces digital images for patients receiving intraoral x-ray examinations for diagnostic purposes. An image analysis software is not part of this submission. When the Jazz Solo digital sensor is to be used in a dental practice, an optional software will be necessary.

Comparison Table

Descriptive Information	DEXIS Digital Sensor	JAZZ SOLO Digital Sensor
510(k) Number	K090458	K163224
Indication for Use	The DEXIS Digital Sensor is a USB-driven digital sensor which is intended to acquire dental intra-oral radiography images. The DEXIS Sensor shall be operated by healthcare, professionals, who are educated and competent to perform the acquisition of dental intra-oral radiographs. The DEXIS Digital Sensor can be used either in combination with special positioning devices to facilitate positioning and alignment with the x- ray beam or it may also be positioned by hand with the assistance of the patient.	The JAZZ SOLO digital sensor is intended to acquire dental intra-oral radiographic images. It can be operated by trained dental professionals for patients receiving intraoral x-ray examinations for diagnostic purposes
Intended Use	The DEXIS Digital Sensor is an indirect converting x-ray detector, e.g. incident x-rays are converted by a scintillating material	The JAZZ SOLO Digital Sensor is a USB-driven digital sensor which is intended to acquire dental intraoral radiography images.

	into (visible) light, this light is coupled optically to a light detection imager based on CMOS technology. The design of the sensor assembly supports the automatic detection of the incident x-rays to generate digital images for dental intra-oral applications. The DEXIS Digital Sensor supports USB 2.0 and USB 1.1 connectivity to personal computers using a dedicated electronic assembly and a sensor software driver. The DEXIS Digital Sensor is a USB-driven digital sensor which is intended to acquire dental intra-oral radiography images. The DEXIS Digital Sensor shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intra-oral radiographs. The DEXIS digital sensor can be used either in combination with	The JAZZ SOLO Digital Sensor shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intraoral radiographs. The JAZZ SOLO Digital Sensor can be used either in combination with the provided JAZZ IMAGING positioners, other universal positioning devices manufactured to facilitate the positioning and alignment with an x-ray beam or it may also be positioned by hand with the assistance of the patient. The JAZZ SOLO Digital Sensor can be used with patients of any age, providing the correct positioning of the sensor in the patient mouth can be realized. JAZZ SOLO Digital Sensor is a suitable diagnostic method and may offer reduced radiation exposure compared to analog procedures.

	special positionip.g devices to facilitate positioning and	
	alignment with the x-ray beam or it may also be positioned by hand with the assistance of the patient.	The JAZZ SOLO Digital Sensor can perform and achieve the same type of two dimensional images as conventional (traditional) film sizes 0, 1 and 2. However the JAZZ SOLO Digital Sensor cannot be used to, or as a substitution for extraoral or other types of dental x-ray. When using the JAZZ SOLO Digital Sensor as a diagnostic aide, clinical experience and a combination of other diagnostic aides should be used to form a diagnosis and should not be solely relied upon for diagnosis.

Manufacturer	Sybron Dental Specialties, Inc.	Jazz Imaging LLC
Trade Name	DEXIS Sensor	JAZZ SOLO Digital Sensor
Classification Name	Extraoral source x-ray system	Extraoral source x-ray system
Classification Panel	Radiology	Radiology
Product Code	MUH	MUH
Regulation Number	21 C.F.R. § 872.1800	21 C.F.R. § 872.1800
Classification	Class II	Class II
Common Name	Digital x-ray sensor	Digital x-ray sensor
Number of Sensors	1	1
Sensor Exterior Size	38.95 mm x 29.75 mm	39.1 mm x 30 mm
Sensor Imaging Size	32.99 mm x 25.82 mm image area with four clipped corners	34.85 mm x 26.28 mm image area with four clipped corners
Overall Imaging Area	820 mm2	873 mm2
Pixel Size	19.5 µm	18 µm
Imager Resolution	1692 by 1324 pixels (2.25 M Pixels)	1936 x 1460 pixels (2.7 M Pixels)
X-Ray Resolution	20+ visible lp/mm	20+ visible lp/mm
Dynamic Range	16,384:1	4096:1
Technology	CMOS	CCD
Scintillator Technology	Cesium Iodide	Cesium Iodide
Interface to PC	USB 2.0, Type A Plug	USB 2.0, Type A Plug
Cable Length	2.8 m	72” Nominal. Extension Supplied
Operating System	Microsoft Windows XP© Microsoft and Windows Vista©	Windows 7, 8 or 10 (32 or 64 Bit)
Power Consumption	1.4 Watts Max	1.4 Watts Max
Sterilization	Not suitable for sterilization	Not suitable for sterilization

Housing	IP68 10993 Biocompatible	IPx7 Equivalent ISO 10993 Biocompatible
Electrical Rating	DC 5V, 350 mA max	DC 5V, 350 mA max

Comparison of MTF and DQE for the DEXIS Sensor and the JAZZ SOLO Sensor

The DEXIS Digital Sensor operates only within its proprietary software application and its closed software application performs extensive manipulation of images from the DEXIS Digital Sensor for viewing purposes only. Its proprietary software application does not allow raw images to be generated for scientific evaluation of characteristics such as MTF and DQE. Without Dexis cooperation, which we will not get, these measurements are not possible.

JAZZ Imaging believes that by comparing the MTV and DQE of the DEXIS Digital Sensor with the MTF and DQE of the JAZZ SOLO Digital Sensor that they are substantially equivalent to each other.

Clinical Testing

Clinical images were provided. These clinical images were not necessary to establish substantial equivalence based on the modifications to the device (note that the x-ray detector technology is similar to predicate). These clinical images provide further evidence in addition to the laboratory performance data to show that the complete system works as intended.

Meaningful Differences

The DEXIS Digital Sensor is an X-ray image sensor (CMOS). The JAZZ SOLO Digital Sensor is an x-ray image sensor (CCD). JAZZ Imaging has compared the MTV and DQE of the DEXIS Digital Sensor with the MTF and DQE of the JAZZ SOLO Digital Sensor and has determined they are substantially equivalent to each other. The JAZZ SOLO Digital Sensor is not only similar in performance as the DEXIS Digital Sensor, but is also safe and effective based on performance testing in accordance with the following reference standards:

Recognition Number 5-70: ISO 14971:2007/(R)2010 (Corrected 4 October 2007), medical devices - applications of risk management to medical devices.

Recognition Number 19-4: ES60601-1:2005/(R)2012 and A1:2012,

c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (IEC 60601-1:2005, mod).

Recognition Number 19-12: IEC 60601-1-2:2007/(R)2012, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests (edition 3).

Recognition Number 5-89: IEC 60601-1-6 Edition 3.1 2013-10, medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability.

Recognition Number 2-156: ISO 10993-1:2009/(R)2013, biological evaluation of medical devices - part 1: evaluation and testing within a risk management process (Biocompatibility).

Recognition Number 5-87: IEC 62366 Edition 1.1 2014-01, Medical devices - application of usability engineering to medical devices.

CB TEST CERTIFICATE for IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1:2005/AMD1:2012 and IEC 62366:2007/AMD1:2014

Reference 510(k) DEXIS Digital Sensor: K090458

Comparison of Safety and Effectiveness to the Predicate Device

Using the above Comparison Table the JAZZ SOLO Digital Sensor can be compared to the predicate device, DEXIS Digital Sensor, with respect to intended use, indications of use, environment of use, limitations of technical performance and technological characteristics and provides more detailed information regarding the basis for the determination of substantial equivalence.

Conclusion:

The JAZZ SOLO Digital Sensor is substantially equivalent to a legally marketed device in the United States. The JAZZ SOLO Digital Sensor is substantially equivalent in intended use, indications for use, safety and effectiveness, and technical characteristics to the DEXIS Digital Sensor marketed by Sybron Dental Specialties, Inc. under its cleared 510(k) submission K090458.