December 10, 2021

Jazz Imaging LLC dba Jazz Imaging
% Mr. W. Edward Johansen
Official Correspondent
W. Edward Johansen
1239 Stanford Street, #205
SANTA MONICA CA 90404

Re: K213637
Trade/Device Name: JAZZ Solo sensor
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: November 16, 2021
Received: November 18, 2021

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 and Part 809); 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,

, for

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213637

Device Name
JAZZ Solo sensor

Indications for Use *(Describe)*

JAZZ Solo 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 that can be displayed, enhanced, printed, and saved.

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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510(k) Summary - K213637

Date Summary Prepared: December 6, 2021

A. Submitter Information

Name: Jazz Imaging LLC dba JAZZ Imaging

Address: 770 Charcot Avenue, San Jose, CA 95131 USA

Contact Person: Todd C. Miller

Corporate Telephone: (567) 234-5299

Official Correspondent: W. Edward Johansen

B. Identification of Device

510(k) Number: K213637

Trade Name: JAZZ Solo sensor

Common Name: Dental digital x-ray sensor

Classification Name: Extraoral source x-ray system Product Code: MUH

Class: II

Panel: Radiology

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

C. Equivalent Legally Marketed Device (Predicate Device)

510(k) Number: K163224

Trade Name: JAZZ SOLO Sensor

Manufacturer: Jazz Imaging LLC dba JAZZ Imaging

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

D. Device Description

The JAZZ Solo sensor, Model 10-002, 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 sensor design uses advanced ergonomic principles with four beveled corners, a moderate profile and a rounded casing providing enhanced comfort for patients. The JAZZ Solo sensor is positioned in the patient's mouth in the same manner as intra-oral film is positioned.

The JAZZ Solo sensor has an x-ray imager (CMOS) 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 sensor through the standard USB port. Image analysis software is not part of the submission. For the JAZZ Solo 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.

Software provides drivers and utilities for x-ray dose optimization, sensor activation and settings. The software of the JAZZ Solo sensor being used is unchanged from the predicate JAZZ SOLO Sensor. Firmware for the JAZZ Solo sensor, which controls basic imager function and readout, has been simplified from the predicate JAZZ SOLO Sensor.

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

E. Indications for Use

The JAZZ Solo 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 that can be displayed, enhanced, printed, and saved.

F. Intended Use

The JAZZ Solo sensor is a USB-driven digital sensor which is intended to acquire dental intraoral radiography images. The JAZZ Solo sensor shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intraoral

radiographs. The JAZZ Solo sensor can be used either in combination with the provided JAZZ IMAGING positioners, other universal positioningdevices manufactured to facilitate the positioning and alignmentwith an x-ray beam, or it may also be positioned by hand with the assistance of the patient. The JAZZ Solo sensor can be used with patients of any age, providing the correct positioning of the sensor in the patient mouth can be realized.

The JAZZ Solo sensor requires a dedicated imaging software package to operate at full potential as a diagnostic imaging device. The imaging software is not included and may need to be purchased separately.

Using a JAZZ Solo sensor is a suitable diagnostic method and may offer reduced radiation exposure compared to analog procedures. Furthermore, available software image enhancement tools may enhance sensitivity and consequently reduce errors introduced by subjective analysis.

When using the JAZZ Solo sensor and software 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.

G. Comparison of Image Qualities

JAZZ Imaging believes that by comparing the MTF, SNR and usable x-ray Dose range of the JAZZ SOLO Sensor with the JAZZ Solo sensor shows that the Image Quality is substantially better in the new JAZZ Solo Sensor.

H. Performance Testing--Clinical

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.

I. Comparison Table

The following comparison table compares the JAZZ Solo sensor to the predicate JAZZ SOLO Sensor with respect to intended use, indications of use, environment of use, limitations of use, technical performance, and technological characteristics and provides more detailed information regarding the basis for the determination of substantial equivalence.

Comparison Chart

Manufacturer	Jazz Imaging LLC	Jazz Imaging LLC
Trade Name	JAZZ SOLO Sensor	JAZZ Solo sensor
Classification Name	Extraoral source x-ray system	Extraoral source x-ray system
Label	Label contains Part Number (10-001), Serial Number and all required regulatory identification	Label contains Part Number (10-002), Serial Number and all required regulatory identification
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	39.1 mm x 30 mm (not including chamfered corners)	39.1 mm x 30 mm (not including chamfered corners)
Sensor Imaging Size	34.85 mm x 26.28 mm image area with four clipped corners	34.9 mm x 26.3 mm (not including chamfered corners)
Overall Imaging Area	873 mm2	873 mm2
Pixel Size	18 µm	18 µm
Imager Resolution	1936 x 1460 pixels (2.7 M Pixels)	1936 x 1460 pixels (2.7 M Pixels)
X-Ray Resolution	20+ visible lp/mm	20+ visible lp/mm
Dynamic Range	4096:1	16384:1
Technology	CCD	CMOS
Scintillator Technology	Cesium Iodide	Cesium Iodide
Interface to PC	USB 2.0, Type A Plug	USB 2.0, Type A Plug
Cable Length	72” Nominal plus 12" Extension Supplied	72” Nominal plus 36” Extension Supplied
Operating System	Windows 7, 8 or 10 (32 or 64 Bit)	Windows 7, 8 or 10 (32 or 64 Bit)
Power Consumption	1.4 Watts Max	0.7 Watts Max
Sterilization	Not suitable for sterilization	Not suitable for sterilization
Housing	IPx7 Equivalent ISO 10993 Biocompatible	IPx7 Equivalent ISO 10993 Biocompatible
Electrical Rating	DC 5V, 350 mA max	DC 5V, 350 mA max

Descriptive Information	Predicate JAZZ SOLO Sensor	JAZZ Solo sensor
Indications for Use	The JAZZ SOLO 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 that can be displayed, enhanced, printed, and saved.	The JAZZ Solo 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 that can be displayed, enhanced, printed, and saved.
Intended Use	The JAZZ SOLO Sensor is a USB-driven digital sensor which is intended to acquire dental intraoral radiography images. The JAZZ SOLO Sensor shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intraoral radiographs. The JAZZ SOLO 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	The JAZZ Solo sensor is a USB-driven digital sensor which is intended to acquire dental intraoral radiography images. The JAZZ Solo sensor shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intraoral radiographs. The JAZZ Solo 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

	positioned by hand with the assistance of the patient. The JAZZ SOLO Sensor can be used with patients of any age, providing the correct positioning of the sensor in the patient mouth can be realized. The JAZZ SOLO 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.	the assistance of the patient. The JAZZ Solo sensor can be used with patients of any age, providing the correct positioning of the sensor in the patient mouth can be realized. The JAZZ Solo sensor requires a dedicated imaging software package to operate at full potential as a diagnostic imaging device. The imaging software is not included and may need to be purchased separately.
	Using a JAZZ SOLO Sensor is a suitable diagnostic method and may offer reduced radiation exposure compared to analog procedures. Furthermore, available software image enhancement tools may enhance sensitivity and consequently reduce errors introduced by subjective analysis.	Using a JAZZ Solo sensor is a suitable diagnostic method and may offer reduced radiation exposure compared to analog procedures. Furthermore, available software image enhancement tools may enhance sensitivity and consequently reduce errors introduced by subjective analysis.
	When using the JAZZ SOLO Sensor and software 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.	When using the JAZZ Solo sensor and software 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.

J. Meaningful Differences

The JAZZ Solo sensor has an x-ray image sensor (CMOS). The predicate JAZZ SOLO Sensor has an x-ray image sensor (CCD). JAZZ Imaging has compared the Image Quality of the Solo sensor with the Image Quality of the predicate JAZZ SOLO Sensor and has determined the Image Quality of the JAZZ Solo Sensor is substantially better. The JAZZ Solo sensor is not only better in performance as the predicate JAZZ SOLO Sensor, but is also safe and effective based on performance testing in accordance with the following reference standards:

FR Recognition Number 19-4: ANSI AAMI 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).

FR Recognition Number 19-8: IEC 60601-1-2 Edition 4.0 2014-02/ IEC60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances - Requirements and tests.

FR 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.

FR Recognition Number 5-114: IEC 62366-1 Edition 1.0 2015-02 Medical devices - Application of usability engineering to medical devices.

FR Recognition Number 2-258: ISO 10993-1 Fifth Edition 2008-08 Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process.

FR Recognition Number 5-40: ISO 14971 Second Edition 2007-03-01/(R)2010 (Corrected 4 October 2007 Medical d devices - Applications of risk management to medical devices.

FR Recognition Number 13-79: IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes.

K. Comparison of Safety and Effectiveness to the Predicate Device

Using the above Comparison Table, the JAZZ Solo sensor can be compared to the predicate JAZZ SOLO 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.

L. Summary of Changes

The USB microprocessor to CMOS of the JAZZ Solo sensor and the USB microprocessor to CCD of the JAZZ SOLO Sensor are identical. The software for the predicate JAZZ SOLO Sensor and the software for the JAZZ Solo sensor are identical. The firmware has been simplified from the firmware of the predicate JAZZ SOLO Sensor. The firmware of the JAZZ Solo sensor controls basic imager function and readout. A single FPGA of the JAZZ Solo sensor controls all CMOS timing, acquisition, readout, and sensor functions.

M. Conclusion

JAZZ Solo sensor image quality is substantially better than the legally marketed predicate JAZZ SOLO Sensor, in the United States. The JAZZ Solo sensor is substantially equivalent in intended use, indications for use, safety and effectiveness, and technical characteristics to the predicate JAZZ SOLO Sensor marketed by Jazz Imaging LLC dba JAZZ Imaging under its cleared 510(k) submission K163224.