November 21, 2024

Jazz Imaging
℅ W. Edward Johansen
Official Correspondent
770 Charcot Ave
SAN JOSE, CA 95131

Re: K241495
Trade/Device Name: Jazz Classic
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: October 23, 2024
Received: October 23, 2024

Dear W. Edward 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241495

Device Name

Jazz Classic

Indications for Use *(Describe)*

Jazz Classic is a clinical software application that captures images and data from Jazz intraoral x-ray sensors and various imaging sources (e.g., radiographic devices, digital still/video capture devices, and generic image devices such as scanners). Jazz Classic enables the storage of images, clinical notes, and clinical exam data. Jazz Classic is intended to be used for general populations which includes use for pediatric populations.

It is intended to acquire, display, edit (e.g., resize, enhance), review, print, and distribute images using standard PC hardware. Jazz Classic is intended for diagnostic and non-diagnostic purposes by dental professionals trained to provide dental care.

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) #: K241495

510(k) Summary

Prepared on: 2024-11-19

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Jazz Imaging
Applicant Address	770 Charcot Ave San Jose CA 95131 United States
Applicant Contact Telephone	(310) 795-7425
Applicant Contact	Mr. W. Edward Johansen
Applicant Contact Email	wedjohansen@msn.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Jazz Classic
Common Name	Dental Imaging Software
Classification Name	Medical Image Management and Processing System
Regulation Number	21 C.F.R. §892.2050
Product Code(s)	LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K110886	CLIO/CLIOSOFT	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

Jazz Classic is a dental imaging software application that equips trained dental professionals with the tools to capture, process, organize, save, and share diagnostic images of patients. The software operates on standard PC hardware and displays images on the PC's connected display or monitor. Images can be acquired from digital dental imaging devices, including intraoral x-ray sensors, dental panoramic and cephalometric scanners, and intraoral cameras. It stores images using lossless compression, and can export them as DICOM, PNG, JPEG, or TIF files. It enables dental practitioners to visualize, annotate, and manipulate patient images to assist in case diagnosis, review, and treatment planning to further enhance the diagnostic value of images.

Jazz Classic integrates with client-server practice management software, bridging patient information from the user's existing practice management solutions to be used for scheduling, clinical note-taking, and billing.

Jazz Classic neither contacts the patient nor controls any life sustaining devices. Diagnosis is not performed by the software but by dentists and other licensed dental professionals.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Jazz Classic is a clinical software application that captures images and data from Jazz intraoral x-ray sensors and various imaging sources (e.g., radiographic devices, digital still/video capture devices, and generic image devices such as scanners). Jazz Classic enables the storage of images, clinical notes, and clinical exam data. Jazz Classic is intended to be used for general populations which includes use for pediatric populations.

It is intended to acquire, display, edit (e.g., resize, enhance), review, print, and distribute images using standard PC hardware. Jazz Classic is intended for diagnostic and non-diagnostic purposes by dental professionals trained to provide dental care.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of Jazz Classic is the same as the predicate device, with few exceptions that do not constitute a new intended use or raise any new or potential risks to the user or patient. The Jazz Classic subject device shares the same intended use as the ClioSoft predicate device. Both devices are intended to acquire, display, edit, review, store, print, and distribute images using standard PC hardware. The subject device is intended for general patient populations, including pediatric patient, whereas the indications for use of the ClioSoft predicate does not specify the intended patient population. Jazz Classic is intended for diagnostic and non-diagnostic use by trained dental professionals who provide dental care, while the predicate device does not specify the intended user of the device.

Technological Comparison

21 CFR 807.92(a)(6)

Jazz Classic and CLIO/CLIOSOFT are intended to enable dentists, dental hygienists, and other dental professionals to capture diagnostic images.

Both software allows for the capture, storage, review, distribution, adjustment, and annotation of dental radiographs and digital still/ video sources. Both integrate with dental imaging TWAIN device for acquiring diagnostic images.

Other similarities include that both Jazz Classic and ClioSoft both process digital images to enhance diagnostic value, both create a database of patients and exam images in patient folders on a server, both software can operate as a stand-alone workstation as well as a client-server-based system, and both offer users database management and storage features.

Some differences between the software applications include the OS versions on which the software operate, cybersecurity features, image compression features, and image templates for pediatric populations. Jazz Classic was developed on a Microsoft .NET platform and only operates on Windows 10 64-bit OS and newer, whereas ClioSoft was developed on a Microsoft platform and operates on Windows XP OS 32-bit and 64-bit architectures. Jazz Classic is capable of lossless image compression when exporting and emailing images, whereas ClioSoft is not. Jazz Classic has cybersecurity detection features whereas ClioSoft does not. Jazz Classic has dedicated imaging templates and tooth numbering systems intended for pediatric populations, whereas ClioSoft does not.

Jazz Classic is a software only medical device. ClioSoft is a software device that is part of an X-ray system, which includes Clio X-ray sensor hardware that connects to a PC.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Jazz Imaging has conducted design verification, bench testing validation and clinical evaluation to confirm that Jazz Classic dental imaging software application is capable of acquiring, displaying, enhancing, reviewing, printing, and distributing diagnostic images.

Verification testing confirmed that the software design requirements have been met.

Bench testing was performed on Jazz Classic and the predicate device, Cliosoft, using images acquired from scientific phantom targets. The results confirmed that Jazz Classic produced superior signal-to-noise ratio (SNR) and resolution compared to the predicate device, validating its image processing capabilities.

Jazz Imaging also performed a clinical evaluation to assess the intended effectiveness of Jazz Classic in a clinical environment. Based on expert opinion, Jazz Classic meets operational and clinical needs to acquire and evaluate dental images safely and effectively.