November 21, 2025

Archy Dental, Inc.
% Robert Packard
President
Medical Device Academy.Inc.
345 Lincoln Hill Rd
SHREWSBURY, VT 05738

Re: K251880
Trade/Device Name: Archy Dental Imaging
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: June 13, 2025
Received: October 22, 2025

Dear Robert Packard:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251880

Device Name
Archy Dental Imaging

Indications for Use *(Describe)*
Archy Dental Imaging is an internet-based, image management software (PACS) that enables dental offices to keep records of hard and soft tissue charts in the form of digital images. The system uses a Web-based interface and includes acquisition, editing, and storage of digital images. Images and data can be stored, communicated, processed, and displayed within the system or across computer networks at distributed locations. Images can be acquired from standard dental imaging devices or can be uploaded directly from the user's computer. Images can be edited (e.g., zoomed, contrast adjusted, rotated, etc.), as well as exported. The system is designed to provide images for diagnostic use.

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.

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510(k) SUMMARY
K251880

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

Company Name: Archy	Archy Dental, Inc.
Address:	3031 Tisch Way, 110 Plaza West
City, State, Zip	San Jose, CA, 95128
Tel:	408-538-7008
Contact Person:	Benjamin Kolin
Prepared By:	Rob Packard
Date Prepared:	11/14/2025

II. DEVICE

Device Trade Name:	Archy Dental Imaging
Classification Name:	Medical image management and processing system
Regulation:	21 CFR 892.2050
Regulatory Class:	II
Device Panel:	Radiology
Product Classification Code:	LLZ

III. PREDICATE DEVICE

Predicate Manufacturer:	Curve Dental
Predicate Trade Name:	Curve Image 2.0
Predicate 510(k):	K112974
Classification Name:	Medical image management and processing system
Regulation:	21 CFR 892.2050
Regulatory Class:	II
Device Panel:	Radiology
Product Classification Code:	LLZ

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Archy Dental Imaging is a cloud-based dental imaging software that allows access to diagnostic radiological and photo images on any PC with an active internet connection via modern web browser. Archy Dental Imaging contains all key features present in traditional client-server based dental imaging software.

Archy Dental Imaging is a Class II dental imaging software that includes the ability to acquire, view, annotate, and organize dental radiographs and color images. Images stored using Archy Dental Imaging are saved using lossless compression and can be exported as DICOM or PNG files. The original images are treated as immutable by the rest of the system.

Archy Dental Imaging is a software-only dental image device which allows the user to acquire images using standard dental imaging devices, such as intraoral X-ray sensors, intraoral cameras, and scanners. Archy Dental Imaging is imaging software designed for use in dentistry. The main Archy Dental Imaging software functionality includes image acquisition, organization, and annotation. Archy Dental Imaging is used by dental professionals for the visualization of patient images retrieved from a dental imaging device or scanner, for assisting in case diagnosis, review, and treatment planning. Dentists and other qualified individuals can display and review images, apply annotations, and manipulate images. Archy Dental Imaging is the imaging component of Archy, a full-featured dental practice management system that handles scheduling, charting, and other practice business concerns. The software operates within a web browser upon standard consumer PC hardware and displays images on the PC's connected display/monitor. The subject device is the Archy Dental Imaging software; the computer or the monitor are not part of the submission.

Archy Dental Imaging neither contacts the patient nor controls any life sustaining devices. Diagnosis is not performed by this software but by doctors and other qualified individuals. A physician, providing ample opportunity for competent human intervention, interpreting images and information being displayed and printed.

V. INDICATIONS FOR USE

Archy Dental Imaging is an internet-based, image management software (PACS) that enables dental offices to keep records of hard and soft tissue charts in the form of digital images. The system uses a Web-based interface and includes acquisition, editing, and storage of digital images. Images and data can be stored, communicated, processed, and displayed within the system or across computer networks at distributed locations. Images can be acquired from standard dental imaging devices or can be uploaded directly from the user's computer. Images can be edited (e.g., zoomed, contrast adjusted, rotated, etc.), as well as exported. The system is designed to provide images for diagnostic use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Archy Dental Imaging (K251880)	Curve Image 2.0 (K112974)	Substantial Equivalence Comparison
Product Code	LLZ	LLZ	Same.
Regulation	21 C.F.R. 892.2050	21 C.F.R. 892.2050	Same
Class	II	II	Same.
Intended Use/ Indications for Use	Archy Dental Imaging is an internet-based, image management software (PACS) that enables dental offices to keep records of hard and soft tissue charts in the form of digital images. The system uses a web-based interface and includes acquisition, editing and storage of digital images. Images and data can be stored, communicated, processed, and displayed within the system or across computer networks at distributed locations. Images can be acquired from standard dental imaging devices or can be uploaded directly from the user's computer. Images can be edited (e.g., zoomed, contrast adjusted, rotated, etc.), as well as exported. The system is designed to provide images for diagnostic use.	CURVE IMAGE is an internet-based, image management software (PACS) that enables dental offices to keep records of hard and soft tissue charts in the form of digital images. The system uses a web-based interface and includes acquisition, editing and storage of digital images. Images and data can be stored, communicated, processed, and displayed within the system or across computer networks at distributed locations. Images can be acquired from standard dental imaging devices or can be uploaded directly from the user's computer. Images can be edited (e.g., zoomed, contrast, rotated, etc.), as well as exported. The system is designed to provide images for diagnostic use.	Same

Environment of Use	Dental offices.	Dental offices.	Same
Performance Characteristics & Principle of Operation	Basic Technology: Web browser-based, software application Features: ● Browsing Images by exam Date ● Viewing an Image ● Uploading an Image file from the local computer ● Acquiring an Image from an intra/extra-oral camera ● Acquiring an Image from a TWAIN Device ● Acquiring an image from standard dental imaging devices ● Copying an Image to the Local Computer Saving a Modified Image	Basic Technology: Web-based, software application Features: ● Browsing Images by Date and/or Source ● Viewing an Image ● Uploading an Image File ● Acquiring an Image from a Web Camera ● Acquiring an Image from a TWAIN Device ● Copying an Image to the Local Computer ● Saving a Modified Image ● Annotating an Image ● Zooming In on an Image ● Inverting Colors of an Image Rotating an Image (increments	There are additional features in the subject device that are not available in the predicate device. The Subject device can archive and unarchive images, the ability to annotate which teeth are displayed in an image, and the ability to provide adaptive histogram, CLAHE, and colorization filters. This feature provides improved user experience and diagnostic capabilities. The additional features in the subject device do not alter the indications for use, impact the safe and effective use of the device.

	• Annotating an Image • Zooming In on an Image • Inverting Colors on an Image • Rotating an Image (increments of 90 degrees) • Flipping an Image Horizontally or Vertically • Increasing/Decreasing Image Brightness • Increasing/Decreasing Image Contrast • Lossless Image Compression • Image exploration filters: adaptive histogram, CLAHE, colorization • Image archive/unarchive • Image tooth annotation	of 90 degrees) • Flipping an Image Horizontally or Vertically • Increasing/Decreasing Image Brightness • Increasing/Decreasing Image Contrast • Lossless image compression	
Technical Characteristics	• Web browser-based application and interface • Secure data transmission (HTTPS) • Database Management and Storage • Secure server and Infrastructure	• Web-based application and interface • Secure data transmission (HTTPS) • Database Management and Storage • Secure server and Infrastructure	Same

Administration	• User login • Account management • Security administration privileges for Administrator, Finance, Staff, and Reporting users • MFA (multi-factor authentication) support for all practice roles	• User login • Account management • Security administration privileges for Administrator, Basic User, Clinical User and Practice Management User	Same
Patient Management	Patient profile and data management	Patient profile and data management	Same
Scheduling	Appointment management functions with calendar	Appointment managements functions with calendar	Same
Billing	Setting up billing and insurance information	Setting up billing and insurance information	Same
Insurance Management	Retrieve insurance payments	Retrieve Insurance payments	Same
Claims Management	Create and manage insurance claims	Create and manage Insurance claims	Same
Dental Charting	Dental Chart layout and treatment plans management	Dental Chart layout and treatment plans management	Same
Perio Charting	Perio chart, perio exam and perio graph management	Perio Chart, perio exam and perio graph management	Same
Patient Notes and History	Patient text notes, note history	Patient text notes, note history	Same

Prescriptions	Prescription integration via DoseSpot	Prescription notepad writer	Same
Summary of Non-Clinical Testing	• Software Risk Assessment • Software Modules Verification Tests • Software Validation Test	• Software Risk Assessment • Software Modules Verification Tests • Software Validation Test	Same
Differences between Two Software	No substantive differences in the two Software	UI Differences	Minor differences in UI in terms of terminology and flow. E.g.: Uses “Mounts” as opposed to “Templates”, Imaging acquisition and viewing are from the same window.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Sterilization & Shelf-life Testing

Not Applicable (Standalone Software)

Biocompatibility Testing

Not Applicable (Standalone Software)

Electrical safety and electromagnetic compatibility (EMC)

Not Applicable (Standalone Software)

Software Verification and Validation Testing

Archy Dental, Inc has conducted comprehensive non-clinical and validation testing of the Archy Dental Imaging system, a PACS designed to reliably post-process and display images for dental applications. Each component of the Archy Dental Imaging software has been thoroughly tested to confirm that the system offers capabilities comparable to those of the predicate device. All of the testing listed below was successful and the test results demonstrate that the subject device is safe and effective.

The tests performed included:

- Software Risk Assessment
- Software verification and validation testing
    - Functional testing
    - Non-functional testing
    - System interface testing
    - Error handling and recovery
    - Compliance testing
    - System testing of unresolved anomalies
- Cybersecurity Penetration Testing
    - Abuse/misuse case testing and malformed/unexpected input handling
    - Robustness testing
    - Fuzz testing
    - Attach surface analysis
    - Vulnerability chaining
    - Closed-box known vulnerability scanning
- Use Related Risk Analysis (URRA)
- Critical Task Analysis
- Clinical Expert Evaluation
    - Clinical Performance
    - Image Quality

- Operational Usability

VIII. CONCLUSIONS

Based on the comparison of intended use, indications for use and technological characteristics, the Archy Dental Imaging software is substantially equivalent to the predicate device.