November 1, 2022

Patterson Dental Supply, Inc.
℅ Erin Daly
Senior Regulatory Manager
Dolphin Imaging & Management Solutions
9200 Oakdale Avenue, Ste 500
CHATSWORTH CA 91311

Re: K221478
Trade/Device Name: Dolphin Blue Imaging 2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: September 26, 2022
Received: September 27, 2022

Dear Erin Daly:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

For

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of 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)*
K221478

Device Name
Dolphin Blue Imaging 2.0

Indications for Use *(Describe)*
Dolphin Blue Imaging 2.0 software is designed for use by specialized dental practices for capturing, storing and presenting patient images and assisting in treatment planning and case diagnosis. Results produced by the software's diagnostic and treatment planning tools are dependent on the interpretation of trained and licensed practitioners.

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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PATTERSON
1031 Mendota Heights Road
Saint Paul, MN 55120
800.328.5536

510(K) SUMMARY

Dolphin Blue Imaging 2.0
K221478

Applicant Information:
Patterson Companies
1031 Mendota Heights Road, Saint Paul, MN 55120
Telephone: (608) 345-4888
Contact: Erin Daly
Date Prepared: September 9, 2022

Trade Name/ Classification:
Proprietary Name: Dolphin Blue Imaging 2.0
Classification Name/ Class: Medical image management and processing system
Common Name: Medical image management and processing system
Regulation Number: 21 CFR 892.2050
Product Code: LLZ
Classification Panel: Radiology Devices

Predicate Device:
Dolphin Blue Imaging 2.0 is substantially equivalent to the following FDA approved predicate devices with regard to indications for use, performance, and technological characteristics.

510K Number: K110430
Trade Name: Dolphin Imaging
Manufacturer: Patterson Dental Supply, Inc.
Classification: II
Regulation Number: 892.2050
Product Code: LLZ
Classification Panel: Radiology Device

Reference Device:

510K Number: K132342
Trade Name: XVWeb
Manufacturer: Apteryx, Inc.
Classification: II
Regulation Number: 892.2050
Product Code: LLZ
Classification Panel: Radiology Device

Table 1- Substantial Equivalence Summary

Device Name	**Dolphin Blue Imaging 2.0** (Proposed device)	**Dolphin Imaging** (Primary Predicate)	**Apteryx** (Reference Predicate)
510(k)	K221478	K110430	K132342
Classification	Device Class: II Classification Code: LLZ	Device Class: II Classification Code: LLZ	Device Class: II Classification Code: LLZ
Intended Use	Dolphin Blue Imaging 2.0 software is designed for use by specialized dental practices for capturing, storing and	Dolphin Imaging software is designed for use by specialized dental practices for capturing,	XVWeb is a Picture Archiving and Communications System (PACS) that enables dental facilities to query and access digitally stored hard and soft

	presenting patient images and assisting in treatment planning and case diagnosis. Results produced by the software's diagnostic and treatment planning tools are dependent on the interpretation of trained and licensed practitioners.	storing and presenting patient images and assisting in treatment planning and case diagnosis. Results produced by the software's diagnostic and treatment planning tools are dependent on the interpretation of trained and licensed practitioners.	tissue intraoral /extraoral radiological images using an internet/web browser. A web-based interface provides users the needed functionality to display patient images and studies in commercially available web browsers. Patient images/studies can be accessed by users locally within the system or across a wide-area network at distributed locations. Acquisition can be included via integration with a DICOM-compatible imaging application or server configured to forward images to the XVWeb database. The system allows users to: manipulate (e.g. rotate, flip, etc.): enhance (e.g. increase or decrease brightness/contrast, gamma correction); add labels (e.g. measurements, lines, arrows, etc.), annotations to patient images/studies and other relevant operations for diagnostic purposes. XVWeb is designed for medium-to-large dental practices and is intended for trained dental professionals and technicians to access, manipulate, and enhance dental images for diagnostic purposes only.
Features			
Image manipulation	Yes	Yes	Yes
Image printing	Yes	Yes	Yes
Cephalometric tracing and analysis	Yes	Yes	N/A
Tracing/Image superimposition	Yes	Yes	N/A
General			
Windows compatible	Yes	Yes	Yes
TWAIN compatible	Yes	Yes	Yes
Predefined and custom analysis tools	Yes	Yes	N/A

Digital imaging software integration capability	Yes	Yes	Yes
Practice management software integration capability	Yes	Yes	Yes
Technical Characteristics			
Web-based application	Yes	No	Yes
Interface Secure data transmission (HTTPS)	Yes	No	Yes
Database Management and Storage Secure server and Infrastructure	Yes	Yes	Yes
Cloud Services	Yes	Yes	Yes

Description of Device:

Dolphin Blue Imaging 2.0 software is designed for use by specialized dental practices for capturing, storing and presenting patient images and assisting in treatment planning and case diagnosis. Results produced by the software's diagnostic and treatment planning tools are dependent on the interpretation of trained and licensed practitioners.

Dolphin Blue Imaging 2.0 is a software that provides imaging, diagnostics, and case presentation capabilities for dental specialty professionals. The Dolphin Blue Imaging 2.0 suite of software products is a collection of modules that together provide a comprehensive toolset for the dental specialty practitioner. Users can easily manage 2D images and x-rays; accurately diagnose and treatment plan, quickly communicate and present cases to patients and referrals, and can work efficiently with colleagues on multidisciplinary cases. The below functionalities make up the medical device modules:

Tracing Module

If a patient record contains a suitable image, cephalometric digitizing can be utilized to define landmarks to establish the locations of specific anatomical features. The inter-relational positions of these landmarks are used to render tracing lines and calculate cephalometric measurements, which are used in diagnosing patients and planning orthodontic and/or surgical procedures. An extensive library of existing cephalometric analyses is included with the software. The Blue Imaging server is used to manipulate the cephalometric landmark data. Storage in the patient's data record is done by utilizing Dolphin Data Storage.

Measurements Module

For images containing cephalometric tracing data, the user can view a list of measurements calculated according to the specific cephalometric analysis selected to view. Since digitized images contain only the locations of specific points (landmarks) on the patient anatomy, measurements lists are calculated in real-time by the Dolphin Blue Ceph server. Calculations take into consideration the race, gender, age, and customizable normal measurement values for a patient to indicate deviations from the accepted normal measurements.

Superimpositions Module

If a patient record contains multiple x-ray images for which cephalometric data has been digitized, the resulting tracings can be overlaid to indicate changes and/or differences in the anatomy. These overlays (superimpositions) are displayed and manipulated within the Dolphin Blue Ceph user interface. The Dolphin Blue Ceph server is responsible for calculating and rendering superimpositions in real-time.

The computer hardware used to access the web application must meet the following requirements:

- Operating System: Windows 10 or newer, Mac OS X (10.1 Yosemite) or newer
- Intel Core i5 Processor
- 8 GB RAM
- 500 GB Hard Drive
- Gigabit Ethernet Adapter
- Screen Resolution 1366x768
- Intel USB Chipset with USB 2.0 Ports (the number of ports needed will be based on what hardware will be used on the workstation)
- Web Browser:
    - Google Chrome (Latest version & latest – 1)
    - *Recommended
    - Microsoft Edge (Latest version & latest – 1)
    - Mozilla Firefox (Latest version & latest – 1)

Indications For Use:

Dolphin Blue Imaging 2.0 software is designed for use by specialized dental practices for capturing, storing and presenting patient images and assisting in treatment planning and case diagnosis. Results produced by the software's diagnostic and treatment planning tools are dependent on the interpretation of trained and licensed practitioners.

Performance Data/Safety and Effectiveness:

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, is included as part of this submission.

Verification and Validation activities have been successfully performed on the software package, including assurance that functions work as designed, performance requirements and specifications have been met, and that all hazard mitigations have been fully implemented. All testing has met the predetermined acceptance values. Traceability of the requirements specified in the requirement specifications and functional specifications is ensured during component integration, software validation and system testing.

Risk Management has been ensured via risk analyses in compliance with ISO 14971 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. Patterson Companies adheres to recognized and established industry standards for development including EN ISO 13485 and IEC 62304.

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Cybersecurity information in accordance with FDA Guidance documents issued October 2, 2014, has been provided. The software has specific cybersecurity controls to prevent unauthorized access, modifications, misuse, or denial of use. Additionally, controls are enabled to prevent the unauthorized use of information that is stored, accessed, or transferred between the software and external devices.

The device is designed and manufactured in accordance with Quality System Regulations as outlined in 21 CFR 820.30.

Dolphin Blue Imaging 2.0 is designed in conformance with the following FDA recognized standards:

Usability (IEC) IEC 62366	Medical devices- Part 1: Application of usability engineering to medical devices
Software (IEC) ANSI/AAMI/IEC 62304: 2006 & A1:2016	Medical device software- Software life cycle process
DICOM (NEMA)	Digital Imaging and Communications in Medicine (DICOM)
Risk Management 14971:2019	Medical devices- Application of risk management to medical devices

All Specifications of Dolphin Blue Imaging 2.0 are verified by several tests before release. Non-clinical testing, including verification tests, evaluated:

- Unit testing
- Performance Testing
- Manual Testing
- Integration Testing
- System and Regression testing

Unit Testing
Engineers perform unit testing before checking in code changes, to validate for the intended functionality. Code changes are validated for compilation upon check-in via an automated build process.

Performance Testing
Performance testing verifies the system stability and response under a specified workload and is conducted for each release. Data sets are utilized while testing several categories and evaluating if the page loads, target counts verify the system stability.

Manual Testing
Manual testing verifies the functions and features of the Dolphin Blue Imaging 2.0 product as an end-user would use the application to verify the software is working as designed and required. Manual tests are pre-defined

Integration Testing
Integration testing verifies the interconnections between applications and systems function correctly and evaluates whether systems or components pass data and control correctly to one another.

System and Regression Testing
System and regression testing are executed as part of the final testing on a release of a product. The plan includes the following as applicable:
a) System Tests executed as regression tests
b) Integration Tests executed as regression tests
c) other tests, such as exploratory testing executed as regression tests

Substantial Equivalence Conclusion:
Dolphin Blue Imaging 2.0 software was designed, developed, tested, and validated according to written procedures. These procedures specify individuals within the organization responsible for developing and approving product specifications, coding, testing, validating, and maintenance. Dolphin Blue Imaging 2.0 has successfully completed integration testing/verification testing and beta validation. In addition, potential hazards have been evaluated and controlled to an acceptable level.

Dolphin Blue Imaging 2.0 has similar function of Cephalometric tracing and analysis and tracing/image superimposition like its predicate device, Dolphin Imaging. Though Dolphin Imaging is a desktop-based software and Dolphin Blue Imaging 2.0 a web-based software, the difference does not raise any new questions regarding safety or effectiveness of the device. Dolphin Blue Imaging 2.0 features were modeled after Dolphin Imaging features. Thus, Dolphin Blue Imaging 2.0 is substantially equivalent to the predicate devices.