August 8, 2022

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

Re: K222072
Trade/Device Name: Dolphin Imaging 12.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: July 13, 2022
Received: July 14, 2022

Dear Ms. 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,

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

K222072

Device Name
Dolphin Imaging 12.0

Indications for Use *(Describe)*

Dolphin Imaging 12.0 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.

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510(K) SUMMARY

Dolphin Imaging 12.0
K222072

Administrative Information

Date Prepared:	13 July 2022
Submitter's Name and Address:	Patterson Companies 1031 Mendota Heights Road Saint Paul, MN 55120 Contact: Erin Daly Telephone: (608) 345-4888
Trade or Proprietary Name:	Dolphin Imaging 12.0
Common or Usual Name:	Dental imaging software
Classification Name:	Medical image management and processing system
CFR Reference:	21 CFR 892.2050
Product Code:	LLZ
Regulatory Class:	Class II
Predicate Device:	K110430 – Dolphin Imaging
Reference Device(s):	Not applicable

Predicate Device Trade or Proprietary Name:	Dolphin Imaging 11.5 K110430
Common or Usual Name:	Dental imaging software
Classification Name:	Medical image management and processing system
CFR Reference:	21 CFR 892.2050
Product Code:	LLZ
Regulatory Class:	Class II

Product Description

Dolphin Imaging 12.0 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 Imaging 12.0 software provides imaging, diagnostics, and case presentation capabilities for dental specialty professionals. The Dolphin Imaging 12.0 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/3D 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:

Description of Medical Device Features

Module	Overview
Cephalometric Tracing	Digitize landmarks on a patient's radiograph, trace cephalometric structures, view cephalometric measurements, superimpose images for analysis and perform custom analysis.
Treatment Simulation (VTO)	Simulate orthodontic and surgical treatment results using Visual Treatment Objective (VTO) and growth features.
Arnett/Gunson FAB Analyses	Perform face, airway, bite (FAB) analysis and simulate treatment for orthodontic and surgical cases based on the methodologies of Dr. William Arnett.
McLaughlin Dental VTO	Analyze and evaluate orthodontic and surgical visual treatment objective (VTO) based on the theories of Dr. Richard McLaughlin.
Implanner™	Plan dental implant procedures in 2D.
Dolphin 3D	Plan, diagnose and present orthodontic and surgical cases, airway analysis, study models, implant planning and surgery treatment simulation in 3D.

Dolphin Imaging 12.0 is a software of Moderate level of concern. Dolphin Imaging maintains all the same key medical device functionality as the predicate Dolphin Imaging 11.5 (K110430). Usability enhancements to the Cephalometric Tracing and Analysis, Treatment Simulation (VTO), and Dolphin 3D modules are included in Dolphin Imaging 12.0, as well as system updates to allow use with current operating software and hardware capabilities

Indications for Use

Dolphin Imaging 12.0 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.

Comparison to Predicate

Parameter	Subject Device K222072 Dolphin Imaging 12.0	Predicate K110430 – 11.5 Dolphin Imaging
Intended Use	Dolphin Imaging 12.0 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 Imaging 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.
Classification	Class II	Class II
Classification Code	LLZ	LLZ
Type of Use (Rx / OTC)	Rx	Rx
User	Orthodontic, oral maxillofacial surgery, and dental-specialty practices.	Orthodontic, oral maxillofacial surgery, and dental-specialty practices.
User Interface/OS	Local PC workstation with 64-bit Microsoft Windows OS	Local PC workstation with Microsoft Windows OS
Medical Device Features		

2D Image Digitize and Measurements	Yes	Yes
2D Image Superimposition	Yes	Yes
2D Growth Forecast	Yes	Yes
2D Treatment Simulation	Yes	Yes
2D Custom Analysis Editor	Yes	Yes
3D Image Digitize and Measurements	Yes	Yes
3D Airway Analysis	Yes	Yes
3D Image (Volume) Superimposition	Yes	Yes
3D Implant Simulation	Yes	Yes
2D/3D Orthognathic Surgical Planning	Yes	Yes

Non-Clinical Performance Testing

Dolphin Imaging 12.0 complies with applicable 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) NEMA PS 3.1-3.20 (2016)	Digital Imaging and Communications in Medicine (DICOM)
Risk Management ISO 14971:2019	Medical devices- Application of risk management to medical devices

Dolphin Imaging 12.0 design and performance verification involved the following tests:

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

Clinical Performance Testing

No clinical testing was required to support substantial equivalence.

Conclusions

Dolphin Imaging 12.0 is substantially equivalent to the predicate device, Dolphin Imaging, and differences do not raise any concerns about safety or efficacy of the device.