January 23, 2025

Cyncronus LLC
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
WARREN, NJ 07059

Re: K241819
Trade/Device Name: CephNinja
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: December 26, 2024
Received: December 26, 2024

Dear Dave Yungvirt:

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.*

510(k) Number *(if known)*
K241819

Device Name
CephNinja

Indications for Use *(Describe)*
CephNinja software is designed for use by dental practices for cephalometric tracing and presenting patient images which are utilized by dental professionals to assist 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. Mobile application is not 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.

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**510(k) Summary: K241819**

## A. Applicant Information

Date Prepared: 23 January 2025

Corporate Name: Cyncronus LLC

Address: 3719 221st Pl SE, Bothell, WA 98021 USA

Device Trade Name: CephNinja

Manufacturer: Cyncronus LLC

Classification Name: Medical image management and processing system

Product Code: LLZ

Common Name: System, Image Processing, Radiological

Classification: Class II

Panel: Radiology

Regulation Number: 21 C.F.R. 892.2050

Submitter/Contact Person: Rohit Madan

Telephone Number: +1 (425) 241-5196

## B. Predicate Device

CephNinja is substantially equivalent to the following FDA cleared SmartCeph predicate with regards to indications for use, intended use, performance and technological characteristics:

Proprietary Name: SmartCeph

Corporate Name: Ortho2, LLC

510(k) Number: K190162

Classification Name: Medical image management and processing system

Product Code: LLZ

Common Name: System, Image Processing, Radiological

Classification: Class II

Panel: Radiology

Regulation Number: 21 C.F.R. 892.2050

**C. Reference Device**

Proprietary Name: Dolphin Blue Imaging 2.0

Corporate Name: Patterson Companies

510(k) Number: K221478

Classification Name: Medical image management and processing system

Product Code: LLZ

Common Name: System, Image Processing, Radiological

Classification: Class II

Panel: Radiology

Regulation Number: 21 C.F.R. 892.2050

**D. Device Description**

CephNinja is a software-only dental image device which allows the user to digitize landmarks on a patient's digital lateral cephalometric x-ray image, trace cephalometric structures, conduct cephalometric analysis, and view cephalometric results. CephNinja is imaging software designed for use in dentistry. The main CephNinja software functionality includes image visualization and cephalometric tracing and measurements. CephNinja is used by dental professionals for the visualization of patient images retrieved from a dental cephalometric imaging device scanner for assisting in case diagnosis, review, and treatment planning for orthodontic and orthognathic applications. If a suitable image file (specifically, a lateral cephalometric x-ray) has been imported into the software, the software can be used to define a number of structures and landmarks to establish specific anatomical features. The positions of specific landmarks are used to render tracing lines and calculate measurements used in orthodontic treatment planning. The software operates on standard Mac/iMac (OS Big Sur M1) hardware, and when not used for diagnostic

purposes, iPhone/iPad (OS 9.0 or higher) hardware. When iMac hardware is used, images are displayed on the connected display/monitor. CephNinja is a standalone product.

## E. Intended Use/Indications for Use

CephNinja software is designed for use by dental practices for cephalometric tracing and presenting patient images which are utilized by dental professionals to assist 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. Mobile application is not for diagnostic use.

## F. Technical Characteristics

CephNinja is a software only device that handles digital medical images. CephNinja neither contacts the patient nor controls any life sustaining devices. Diagnosis is not performed by this software but rather by doctors and other qualified individuals. A physician, providing ample opportunity for competent human intervention, interprets images and information being displayed.

CephNinja allows the user to digitize landmarks on a patient's digital lateral cephalometric x-ray image, trace cephalometric structures, conduct cephalometric analysis, and view cephalometric results.

CephNinja is a macOS/iOS/iPadOS Executable written in Objective C, Swift, C++ language that is intended for use on modern Macs/iMacs, and when not used for diagnostic purposes, iPhones/iPads. CephNinja operates on most computer workstations with minimum specifications of macOS Big Sur M1 and operates on most iPhones/iPads with OS 9.0 or higher.

## G. Recognized Standards

CephNinja is software that conforms to the following recognized standards:

ISO 14971 Medical Devices-Application of Risk Management to Medical Devices

IEC 62304 Medical Device Software Life Cycle Processes

## H. Comparing the SmartCeph Predicate and Dolphin Blue Imaging 2.0 Reference Device to CephNinja

**Table 1** below compares CephNinja to the predicate device, SmartCeph. **Table 2** compares the subject CephNinja device with the reference device, Dolphin Blue Imaging 2.0 (K221478).

Following the comparison tables is a substantial equivalence discussion that further elaborates on details in the tables and discusses how those details support a determination that the subject and predicate devices are substantially equivalent.

**Table 1. Comparison of Subject and Predicate Device**

| | **Subject Device** | **Predicate Device** |
|---|---|---|
| **510(k) Number** | K241819 | K190162 |
| **Trade/Device Name** | CephNinja | SmartCeph |
| **Intended Use** | CephNinja software is designed for use by dental practices for cephalometric tracing and presenting patient images which are utilized by dental professionals to assist 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 dental practitioners. Mobile application is not for diagnostic use. | SmartCeph software is designed for use by dental practices for cephalometric tracing and presenting patient images which are utilized by dental professionals to assist 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 dental practitioners. |
| **Operating System** | macOS, iPadOS, iOS | Windows |
| **User Interface** | Mouse, Keyboard | Mouse, Keyboard |
| **Indications for Use** | CephNinja software is designed for use by dental practices for cephalometric tracing and presenting patient images which are utilized by dental professionals to assist 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. Mobile application is not for diagnostic use. | SmartCeph software is designed for use by dental practices for cephalometric tracing and presenting patient images which are utilized by dental professionals to assist 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. |
| **Technology Platform** | Mac/Apple based | PC |
| **Image Rendering** | 2D | 2D |
| **Image Manipulation** | Preview, Rotate, Enhance, Zoom, Brightness, Contrast, Sharpness | Preview, Rotate, Enhance, Zoom, Brightness, Contrast, Sharpness |
| **Basic Image Measurement** | Distance, angle | Distance, angle |

| | | |
|---|---|---|
| **Standalone Software** | Yes | Yes |
| **Cephalometric Measurement** | Distance, angle, ratio, difference | Distance, angle, ratio, difference |
| **Cephalometric Tracing** | Manual point picking and structure/outline drawing. Software provides predefined structures that can be manually moved around the cephalogram. | Manual point picking, auto and manual structure drawing. Software provides predefined landmarks, structures and allows user to define their own. |
| **Cephalometric Analysis** | Provides 2D analysis on photo or lateral x-ray. User-configurable and standard orthodontic tracing analyses including:<br>- Downs<br>- McNamara<br>- Ricketts<br>- Steiner<br>- Tweed<br>- Wits<br>- Jarabak's<br>- Burstone's/COGS<br>- Alexander<br>- Composite | Provides 2D analysis on photo or lateral x-ray. User-configurable and standard orthodontic tracing analyses including:<br>- ABO Analysis<br>- Alabama<br>- Downs<br>- McLaughlin<br>- McNamara<br>- Ricketts<br>- Steiner<br>- Tweed<br>- Wits |
| **Tracing Superimposition** | Yes | Yes |
| **Wiggle Gram** | No | Yes |
| **2D Growth Simulation** | No | No |
| **Treatment Planning and Simulation** | Orthodontic and orthognathic applications using predefined and custom analysis. No simulation. | Orthodontic and orthognathic applications using predefined and custom analysis. No simulation. |
| **Soft Tissue Deformation** | No | No |
| **Photo Wrapping** | No | No |
| **Implant Module** | No | No |
| **Scanner Connection** | No | No |
| **DICOM Support** | No | No |
| **Regulation Number** | 21 CFR 892.2050 | 21 CFR 892.2050 |
| **Regulation Name: System** | Medical image management and processing system | Medical image management and processing system |
| **Regulatory Class** | Class II | Class II |
| **Product Code** | LLZ | LLZ |
| **Manufacturer** | Cyncronus LLC | Ortho2, LLC |

**Table 2. Comparison of Subject and Reference Device**

| | **Subject Device: CephNinja** | **Reference Device: Dolphin Blue Imaging 2.0** |
|---|---|---|
| **510(k) Number** | K241819 | K221478 |
| **Operating System** | macOS, iPadOS, iOS | Mac OS or any other computing platform operating system |
| **User Interface** | Mouse, Keyboard | Mouse, Keyboard |
| **Technology Platform** | Mac/Apple based | Mac/Apple based<br>or any other computing platform |
| **Image Rendering** | 2D | 2D |
| **Image Manipulation** | Preview, Rotate, Enhance, Zoom, Brightness, Contrast, Sharpness | Preview, Rotate, Enhance, Zoom, Brightness, Contrast, Sharpness |
| **Basic Image Measurement** | Distance, angle | Distance, angle |
| **Standalone Software** | Yes | Yes |
| **Cephalometric Measurement** | Distance, angle, ratio, difference | Distance, angle, ratio, difference |
| **Cephalometric Tracing** | Manual point picking and structure/outline drawing. Software provides predefined structures that can be manually moved around the cephalogram. | Manual point picking, auto and manual structure drawing. Inter-relational positions of these landmarks are used to render tracing lines. |
| **Cephalometric Analysis** | Provides 2D analysis on photo or lateral x-ray. User-configurable and standard orthodontic tracing analyses including:<br>- Downs<br>- McNamara<br>- Ricketts<br>- Steiner<br>- Tweed<br>- Wits<br>- Jarabak<br>- Burstone/COGS<br>- Alexander<br>- Composite | Provides 2D analysis on photo or lateral x-ray. User-configurable and standard orthodontic tracing analyses including:<br>- Ricketts<br>- McNamara<br>- Steiner (Tweed)<br>- Jarabak<br>- Roth<br>- Sassouni<br>- McLaughlin<br>- Downs-Northwestern<br>- Bjork<br>- Alexander (Vari-Simplex)<br>- Holdaway<br>- Alabama<br>- Burstone<br>- Gerety<br>- and ~400 others |

| | | |
|---|---|---|
| **Tracing Super-imposition** | Yes | Yes |
| **Wiggle Gram** | No | Yes |
| **2D Growth Simulation** | No | No |
| **Treatment Planning and Simulation** | Orthodontic and orthognathic applications using predefined and custom analysis. No simulation. | Orthodontic and orthognathic applications using predefined and custom analysis. No simulation. |
| **Soft Tissue Deformation** | No | No |
| **Photo Wrapping** | No | No |
| **Implant Module** | No | No |
| **Scanner Connection** | No | Yes |
| **DICOM Support** | No | Yes |
| **Regulation Number** | 21 CFR 892.2050 | 21 CFR 892.2050 |
| **Regulation Name: System** | Medical image management and processing system | Medical image management and processing system |
| **Regulatory Class** | Class II | Class II |
| **Product Code** | LLZ | LLZ |
| **Manufacturer** | Cyncronus LLC | PATTERSON DENTAL SUPPLY, INC. |

## I. Substantial Equivalence Discussion

There are some differences between CephNinja and the SmartCeph predicate such that CephNinja does not operate on PC platforms with Windows operating systems but rather on Mac/Apple based platforms and operating systems.

CephNinja can be operated on desktop and mobile platforms with a mouse/keyboard, trackpad, or touchscreen interface, but mobile platforms are not indicated for diagnostic use. The SmartCeph predicate can be operated only on desktop platforms with a mouse/keyboard interface.

CephNinja does not feature some of the cephalometric analyses featured in the SmartCeph predicate such as the ABO, Alabama, and McLaughlin analyses.

Both CephNinja and the SmartCeph predicate perform cephalometric analyses on 2D images only.

Like the SmartCeph predicate, CephNinja provides tracing superimposition. However, CephNinja does not provide wiggle gram features like SmartCeph.

None of the above-mentioned differences change the safety, effectiveness, or indications for use of CephNinja as compared to the SmartCeph predicate.

**Table 1** compares CephNinja to the SmartCeph predicate with respect to intended use, indications for use, environment of use, limitations of use, and technological characteristics. This comparison table provides additional information regarding the basis for the determination of substantial equivalence. As shown in **Table 2**, the characteristics of CephNinja are also highly similar to the reference device characteristics.

Although there are some differences between CephNinja and the SmartCeph predicate, the subject CephNinja device and the SmartCeph predicate are substantially equivalent as demonstrated by comparison of the intended use, indications for use, device description, technical characteristics, and performance testing of the devices.

**J. Summary of Performance Testing**

All the different components of CephNinja have been stress tested to ensure that it provides all the capabilities necessary to operate in a manner substantially equivalent to the SmartCeph predicate.

Using a risk-based approach and general use of *ISO 14971-19 Medical Devices-Application of Risk Management to Medical Devices*, the CephNinja safety hazard analysis has identified and sufficiently mitigated risks to users (i.e., overall risks reduced to low). CephNinja has successfully passed software unit, integration, and system level verification and validation testing according to test-specific *a priori* pass/fail criteria in accordance with FDA guidance document, "*General Principles of Software Validation*" and general use of *IEC 62304-06 Medical Device Software Life Cycle Processes* standard.

CephNinja cybersecurity hazards have been evaluated and controlled to an acceptable level (i.e., low risk) in accordance with FDA guidance document, "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*". Cybersecurity risks were identified and suitably addressed though penetration and vulnerability testing activities, and all implemented security controls have passed testing with pre-determined pass/fail criteria.

Non-clinical bench testing of CephNinja included evaluation of device outputs when compared to the conventional reference standard of manual tracing (i.e., all differences in individual angular

and linear measurement values between the measurement methods must be within the clinically meaningful threshold of <2 degrees and <2 mm, respectively).

Overall, the technical performance evaluation of CephNinja demonstrated that CephNinja is an SaMD with good validity, generating relevant outputs for assisting in orthodontic treatment planning and case diagnosis in the clinical practice setting. The accurate, reliable, and precise output data produced by CephNinja has been shown to achieve its intended purpose of supporting clinical decision-making for orthodontic patients.

## K. Conclusion

Based on the comparison of intended use, indications for use, and technological characteristics, CephNinja is substantially equivalent to the SmartCeph predicate. Cyncronus LLC has conducted extensive performance, verification, and validation testing demonstrating that CephNinja provides reliable post-processing information to ensure that it operates in a manner substantially equivalent to the SmartCeph predicate.