Orthofix Srl
Elvira Taccarelli
Regulatory Affairs Manager
Via delle Nazioni, 9
Bussolengo, VR 37012
Italy

December 19, 2024

Re: K242270
Trade/Device Name: OrthoNext Platform System
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: November 19, 2024
Received: November 19, 2024

Dear Elvira Taccarelli:

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,

Jessica Lamb
Assistant Director
Imaging Software 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)*
K242270

Device Name
OrthoNext™ Platform System

Indications for Use *(Describe)*
The OrthoNext™ Platform System is indicated for assisting healthcare professionals in preoperative planning of orthopedic surgery and post-operative planning of orthopedic treatment. The device allows for overlaying of Orthofix Product templates on radiological images, and includes tools for performing measurements on the image and for positioning the template. Clinical judgments and experience are required to properly use the software.

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.

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ORTHONEXT™ PLATFORM SYSTEM

510(k) SUMMARY

Submitter information

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Date prepared	2024, November 19th

Trade Name, Common Name, Classification

Trade Name:	OrthoNext™ Platform System
Classification Regulation Number:	21 CFR 892.2050
Regulation name:	Medical image management and processing system.
Review Panel:	Radiology
Product Code:	QIH
Device Class:	Class II
Device Classification Name	Automated radiological image processing software

Primary Predicate

Primary Predicate	510(k) Number	Manufacturer
OrthoNext™ Platform System	K202519	Orthofix S.r.l.

Reference device

Reference Device	510(k) Number	Manufacturer
Orthofix TrueLok Hexapod System (TL-HEX) V2.0	K170650	Orthofix S.r.l.

Device description	The subject OrthoNext™ Platform System is a web-based modular software system, indicated for assisting healthcare professionals in planning of orthopedic surgery and treatment both preoperatively and postoperatively, including deformity analysis and correction with several Orthofix products. The subject software system is intended for use by Healthcare Professionals (HCP), with full awareness of the appropriate orthopedic procedures, in the operating theatre only. The subject software functions are intended to inform the HCP on orthopedic procedure treatment planning when the Orthofix external or internal fixation systems are used. These functions are evidence-based tools that support HCP when considering treatment digital planning options for a patient. The software functions do not treat a patient or determine a patient's treatment. The software enables the HCP to import radiological images, display 2D views (frontal and lateral) of the radiological images, overlay the positioning of the template and simulate the treatment plan option, and to generate parameters and/or measurements to be verified or adjusted by the HCP based on their clinical judgment.
Indications for use	The OrthoNext™ Platform System is indicated for assisting healthcare professionals in preoperative planning of orthopedic surgery and post-operative planning of orthopedic treatment. The device allows for overlaying of Orthofix Product templates on radiological images, and includes tools for performing measurements on the image and for positioning the template. Clinical judgments and experience are required to properly use the software.
Comparison of Technological Characteristics with the Predicate Device	The following table provides a comparison of technological characteristics of the subject and the primary predicate device. Any differences have been demonstrated to not raise different questions of safety and effectiveness by virtue of objective evidence.

Technological Characteristics		Subject Device OrthoNext™ Platform System	Primary Predicate Device OrthoNext™ Platform System (K202519)
1.	Indications for use	The OrthoNext™ Platform system is indicated for assisting healthcare professionals in preoperative planning of orthopedic surgery and post-operative planning of orthopedic treatment. The device allows for overlaying of Orthofix Product templates on radiological images, and includes tools for performing measurements on the image and for positioning the template. Clinical judgments and experience are required to properly use the software.	The OrthoNext™ Platform system is indicated for assisting healthcare professionals in preoperative planning of orthopedic surgery. The device allows for overlaying of Orthofix Product templates on radiological images, and includes tools for performing measurements on the image and for positioning the template. Clinical judgments and experience are required to properly use the software. The OrthoNext™ Platform system is not to be used for mammography.
	Assessment: The subject indications for use include "post-operative planning of orthopedic treatment", a feature already included in the scope of the reference device, without substantially changing the intended use of the device, which remains intended for assisting healthcare professionals in orthopedic procedure (surgery and treatment) planning. The difference in the type of treatment planning does not constitute a new intended use. The statement "The OrthoNext™ Platform system is not to be used for mammography" included in the original Indications for Use of the primary predicate device was not incorporated in the Indications for Use of the subject device because it was specifically addressed in a dedicated section of the Instructions for Use; as the primary predicate device, the subject device is not to be used for mammography. Equivalent - no significant new questions have been raised.		
2.	Population to be treated	OrthoNext™ Platform System does not directly interact with patients. Software planning functionalities are applicable to patients that need pre-operative orthopedic surgery planning or post-operative orthopedic treatment planning.	OrthoNext™ Platform System does not directly interact with patients. Software planning functionalities are applicable to patients that need pre-operative orthopedic surgery planning.
	Assessment: in comparison to the predicate device, the subject patient population explicitly includes patients needing postoperative orthopedic treatment planning, as in the reference device. The population that undergoes postoperative treatment is the same (or a subgroup) of the population needing preoperative planning, thus it can be considered already included in the patient population of the primary predicate device. Equivalent - no significant new questions have been raised.		
3.	Principle of Operation	Principle of operation: • Importation medical images format (x-ray images) • Processing tools • Measurements and parameters analysis tools • Surgical planning tools • Enable software modules (preoperative and postoperative) for overlaying template for simulation.	Principle of operation: • Importation medical images format (x-ray images) • Processing tools • Measurements and parameters analysis tools • Surgical planning tools • Enable software modules (preoperative and postoperative) for overlaying template for simulation.

	Assessment: The subject device has the same principle of operation of the primary predicate. Equivalent - no significant new questions have been raised.		
4.	Configuration and mode of access	Web-based: login is possible through access to a website by username and password licensed by the manufacturer. The device is not incorporated into IT-Networks.	Web-based: login is possible through access to a website by username and password licensed by the manufacturer. The device is not incorporated into IT-Networks.
	Assessment: The configuration and mode of access of the subject device is the same as the predicate device. Equivalent - no significant new questions have been raised.		
5.	Supported devices	PC/Mac/Tablet	PC/Mac
	Assessment: the main supported platforms are PC/Mac, as the primary predicate device. The subject device is also validated for use on a tablet: since the software is web-based, access is allowed via a login to the same web portal, independently from the platform used. Equivalent - no significant new questions have been raised.		
6.	Operating Systems	Windows (Microsoft) - Minimum Windows 10; macOS (Apple) - Minimum macOS Big Sur (version 11); iPad (Apple) - Minimum 15.8	Windows (Microsoft) - Minimum Windows 10; macOS (Apple) - Minimum macOS Big Sur (version 11)
	Assessment: the supported operating systems are the same (Windows, macOS) in comparison to the primary predicate. The subject device is also validated for use on a tablet, thus also a dedicated operating system is included. Equivalent - no significant new questions have been raised.		
7.	Supported browsers	• Google Chrome v120 or higher (Windows) • Microsoft Edge v121 or higher (Windows) • Firefox v122 or higher (Windows) • Safari 17.2 or higher (macOS) • Mobile Safari 15.8 or higher (iPadOS) - Web Graphics Library (WebGL) enabled NOTE: Web Graphics Library (WebGL) availability and minimum screen resolution are checked at login time in order to provide access to the SW.	• Google Chrome Browser Version 83 or higher (Windows) • Microsoft Edge Version 44 or higher (Windows) • Mozilla Firefox Version 77 or higher (Windows) • Safari Version 13 or higher (macOS) - Web Graphics Library (WebGL) enabled NOTE: Web Graphics Library (WebGL) availability and minimum screen resolution are checked at login time in order to provide access to the SW.
	Assessment: The supported browsers are the same in comparison with the primary predicate, with updated versions. The subject device is also validated for use on a tablet, thus also a dedicated browser is included. Equivalent - no significant new questions have been raised.		

8.	System requirements	Computer System Requirements Display Settings: Screen Resolution of 1280 x 768 pixels or higher. Internet Connection: Minimum required internet connectivity speed of 512 kbps Recommended internet connectivity speed of 3 mbps or higher	Computer System Requirements Display Settings: Screen Resolution of 1280 x 768 pixels or higher. Internet Connection: Minimum required internet connectivity speed of 512 kbps Recommended internet connectivity speed of 3 mbps or higher
	Assessment: The subject device system requirements are identical to the primary predicate device. Equivalent - no significant new questions have been raised.		
9.	Image input	Can receive digital images in .png or .jpg format	Can receive digital images in .png or .jpg format
	Assessment: Subject device image input management is identical to the primary predicate device. Equivalent - no significant new questions have been raised.		

Performance Data	The following performance data were provided in support of substantial equivalence determination. **Accuracy, Sensitivity and Specificity** OrthoNext Platform System software provides users with a set of tools that allow for manual linear and angular measurements on X-ray images. The information derived from the software must be clinically reviewed regarding its plausibility before use in treating patients. Accuracy: the overall accuracy of the system's measurements was verified under a representative worst-case scenario. The following acceptance criteria have been met. For measurements made using anatomical axes: • The mean error is 0.1 mm for linear measurements and 0.05 degrees for angular measurements. • The mean percentage error is 0.24% with a threshold of 0.27% (within the 95th percentile) for linear measurements and 0.08% with a threshold of 1% (within the 95th percentile) for angular measurements. For measurements made using mechanical axes: • The mean error is 0.4 mm for linear measurements and 0.06 degrees for angular measurements. • The mean percentage error is 1.73% with a threshold of 16.67% (within the 95th percentile) for linear measurements and 0.28% with a threshold of 1.27% (within the 95th percentile) for angular measurements. Sensitivity: the sensitivity of the subject device is 1 mm for linear measurements and 1 degree for angular measurements. Specificity: since the device does not perform automated measurements, specificity is not directly applicable in this context. The subject device requires active user involvement for each measurement, and the ability to perform accurate measurements relies entirely on the user's expertise and clinical interpretation. In addition, considerations on accuracy, specificity and sensitivity of the AI/ML algorithm for the automatic marker detection have been included in the submission: • AI/ML Algorithm Accuracy: 0.8 • AI/ML Algorithm Specificity (Precision): 1 • AI/ML Algorithm Sensitivity (TPR): 0.75 **Validation of Machine Learning derived outputs** Performance testing for the magnification marker detection algorithm was conducted using 1000 X-ray images (see table below). Acceptance Criteria: The goal was to achieve zero false positives in the test set of 1000 X-ray images, resulting in a precision of 1. Training Set Composition: The training set included 1500 X-ray images with random areas depicting magnification markers. The 1500 magnification marker have been randomly overlaid on top of 4000 x-Ray images. Image augmentation techniques, such as random rotations and brightness adjustments, generated 24000 unique X-ray images. Each synthetic image is unique, validated by a hash check, where if the hash of two images shows a similarity > 90%, the image is discarded.

Testing and Training Independence: The model was trained using synthetic images, while the test set consisted of real X-ray images that were not used during training, ensuring independence.

Equipment and Protocols: A study on the distribution of magnification marker intensities produced the following results (0 = black; 255 = white).

N° of Samples	Mean value [0-255]	Median Vaue [0-255]
24000	190	193

Clinical Subgroups Information: The focus of this model is solely on the magnification marker; therefore, a statistical analysis and distribution of characteristics such as age, sex, gender, and ethnicity are not applicable. Below is the data regarding the geometrical properties of the magnification marker for both the training and test sets.

Training Set, Sample size = 24000.

Statistic	Value
Mean Diameter [px]	70
Median Diameter [px]	71
Mean Area [px^2]	4105
Median Area [px^2]	3959
Mean Brightness	190
Median Brightness	193

Test Set, Sample size = 800; 200 images of the Test set didn't depict a magnification marker

Statistic	Value
Mean Diameter [px]	40.37
Median Diameter [px]	42.23
Diameter Std. Deviation [px]	11.16
Mean Area [px^2]	1377.48
Median Area [px^2]	1400.69
Area Std. Deviation [px^2]	692.44
Mean Brightness	192
Median Brightness	194

Performance Testing Summary:

Candidate Model – Threshold Value = 0.96	
Precision	1
Accuracy	0.8
TPR/Recall	0.75
FPR	0
F1 Score	0.86

The candidate model produced the following statistics when evaluated on the ground truth values of the Test Set:

Intersection over Union (%)	Center MAE (px)	Center MAPE (%)	Radius MAE (px)	Radius MAPE (%)
79	4.83	0.38	1.29	3

The 3% Radius MAPE (Mean Absolute Percentage Error), when evaluated on the mean value and mean ± 1 standard deviation of the test set distribution, contributes to an error of less than 1 mm.

Ground Truth Annotation Process: The truthing process was conducted by qualified personnel, who carefully overlaid a circular shape on each magnification marker using annotation software. A review and discard process has been implemented to ensure the quality of the annotations.

Software Verification and Validation Testing

Software verification and validation testing of the subject device OrthoNext™ Platform System have been performed as outlined below to demonstrate equivalence in function and safety in respect to its primary predicate device (K202519).

The subject device was developed following the requirements of international standard ANSI AAMI IEC 62304:2006 + A1:2016 "Medical device software — Software life cycle processes", as the primary predicate device.

During the development of the subject device, the manufacturer performed software verification testing according to the relevant FDA Guidances "*Content of Premarket Submissions for Device Software Functions*", issued on June 14, 2023, and "*General Principles of Software Validation*", issued in January 2002, to ensure that the software design output meets input of the subject OrthoNext™ Platform System and mitigates the associated risks in the scope of its intended use.

A link between software Product Requirements (Customer requirements), Software Requirements Specifications (SRS), identified hazard and mitigations, and Software verification and validations testing is provided for the subject device within the Traceability Matrix of OrthoNext™ Platform System, as evidence of the correct and complete implementation of the Software Requirements Specifications (SRS) and Product Requirements.

Design validation activities for the subject OrthoNext™ Platform System were performed in accordance with the Design Validation Plan and Design Validation Protocol, to establish that the software specifications conform to user needs and intended use, confirming proper operation of the software in its actual or simulated use environment.
Validation activities consisted of two different validation scenarios: the software validation during the software testing activities and the "surgeons validation" to confirm the fulfillment of the product to investigate use errors during simulated use, according to standard IEC 62366-1 "*Medical devices- Application of usability engineering to medical devices*".
For software validation, each product requirement was related to the relevant Software Requirements Specifications (SRS) / User story, to verify if users performed each task. Based on the results presented, all the requirements defined as eligible for user design validation have been satisfactorily tested.

	Software usability activities have been conducted at the same time, asking surgeons to perform some specified tasks, answer to some questions in written form, navigate through the software and inviting them to describe ease of use or concerns regarding tasks they are invited to perform. Feedback has been collected in written form together with the answers rating and was analyzed in the Summative Usability Report. Given the overall analysis, Orthofix concluded that the design verification and validation results are acceptable, and that the usability test gave objective evidence that the device usability requirements are met as far as safety of the user interface of the subject OrthoNext™ Platform System is concerned.
Conclusions	Based upon: intended use, conditions of use, patient population, basic software design, operating principle, and non-clinical performance data, the subject OrthoNext™ Platform System has been shown to be substantially equivalent to the legally marketed primary predicate device (K202519).