Orthofix Srl
℅ Ms. Cheryl Wagoner
Consultant
Wagoner Consulting LLC
P O Box 15729
WILMINGTON NC 28408

October 27, 2020

Re: K202519
Trade/Device Name: OrthoNext™ Platform System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 25, 2020
Received: September 1, 2020

Dear Ms. Wagoner:

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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K202519

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. 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.

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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510(k) Summary (21 CFR 807.92)

Submitter information K202519

Submitter Name	Orthofix Srl
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Email address	GianlucaRicadona@orthofix.it
Date of submission	October 22, 2020

Trade Name, Common Name, Classification

Trade Name	OrthoNext ™ Platform system
Device Classification name	Image Processing System Radiological
Product code	LLZ
Panel Code	Radiology
Class	Class II
Classification Regulation Number	21 CFR § 892.2050

Predicate devices

Primary Predicate Device	**510(k) Number**	**Manufacturer**
TraumaCad Mobile 1.0	K142923	ORTHOCRAT,LTD. 291Hillside Avenue Somerset, MA 02726
Additional Predicate Device		
TraumaCAD Version 2.0	K073714	ORTHOCRAT,LTD. 291Hillside Avenue Somerset, MA 02726

Device description	The OrthoNext ™ Platform is a web-based platform module system, to allow surgeons to evaluate digital images while performing various pre-operative treatment planning, evaluation of images and post-operative treatment planning. This software application enables surgeons to import radiological images, display various 2D views of the images, overlays the positioning of the Orthofix devices template and simulate the treatment options, generate parameters and/or measurements to be verified or adjusted by the surgeons based on their clinical judgment.
Indications for use	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.

Technological Characteristics and Intended Use	The OrthoNext™ Platform operating principles and technological characteristic, including the intended use and users are the same as, or similar to, the chosen predicate devices. Summary of the equivalence in technological characteristics and Intended Use: ✓ Intended use: identical. ✓ Operating principles, technological characteristics and conditions of use are substantially equivalent to predicates: the OrthoNext ™ Platform system is a web-based software executed on a common web browser (Chrome, Internet Explorer, Safari), intended to run on a PC, MAC by Windows and Mac OS package , accessible in a secure environment by a license activation code and password provided by the manufacturer. Principle of operation includes: • Importation medical images format (x-ray images) • Processing tools • Measurements and parameters analysis tools • Surgical planning tools • Enable SW Modules (operative treatment planning) for overlaying template for simulation.
Performance Analysis	Subject device has similar configuration, and operating principle as the predicate device. Non-clinical software testing on operative treatment planning of orthopedic surgery using OrthoNext ™ Platform system produces results comparable to planning using acetate overlays but with the additional advantages of digital planning and simulations including ease of use, library, case documentation, access to a wider arrange of tools, and secure accessibility. Any potential hazards have been evaluated and controlled through Risk Management activities. The review of clinical literatures on similar devices support the clinical performance of the Subject device with no additional clinical data. Usability testing have been performed by simulating a clinical environment requiring the test participants to perform treatment planning on X-rays by overlaying the Orthofix product templates.

Basis for Substantial Equivalence

	SUBJECT DEVICE	**PRIMARY PREDICATE DEVICE**
System Features	OrthoNext ™ Platform	TraumaCad Mobile 1.0
Product Code	LLZ	Identical
Indications for Use	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	Identical
Intended Enviroment	Hospital	Identical

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE
Specialties Sites	Easy-to-use solutions for various orthopedic subspecialties for skeletal appendicular trauma and deformity analysis	Identical
Configuration	Web- based	Identical
Image Input	Can receive digital images	Identical
Run on server	YES	Identical
Digital Device Template	YES	Identical
Interactive Template positioning	YES	Identical
Automatic scaling	YES	Identical
Template support from the manufacturer	YES	Identical
Permits template rotation	YES	Identical
Treatment operative planning	YES	Identical
Patient contacting	NO	Identical
Control of Life-Saving Devices	NO	Identical
HCP intervention for interpretation and manipulation of images	YES	Identical

Conclusion	The successful non-clinical testing demonstrates the safety and effectiveness of the OrthoNext ™ Platform system when used for the defined indications for use and demonstrates that the subject device, for which this Traditional 510(k) is submitted, performs as well as or better than the legally marketed predicate devices. OrthoNext ™ Platform contains a subset of the same features and algorithms as those that are in the predicate devices. The testing for each release consisted of Unit, System/Integration and Acceptance test levels. Testing included also security, negative testing, error message handling, stress testing, platform testing, workflow testing, functional testing, multi-user/external access testing, data integrity testing, compatibility testing, load testing, regression testing, and hazard mitigation testing. In case a test was failed any necessary corrections were made, the relevant test was executed and repeated again until all passed.