Orthofix US LLC
℅ Shant Aghyarian
Regulatory Affairs Program Manager
3451 Plano Parkway
LEWISVILLE TX 75056

September 26, 2023

Re: K230252
Trade/Device Name: OFIX MIS App
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: January 31, 2023
Received: August 30, 2023

Dear Shant Aghyarian:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software 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.

Submission Number *(if known)*

K230252

Device Name

OFIX MIS App

Indications for Use *(Describe)*

The OFIX MIS App software assists healthcare professionals in viewing, storing, and measuring images as well as planning orthopedic surgeries. The app allows service providers to plan surgical procedures by making measurements for the placement of surgical implants. Clinical judgement 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

K230252

OFIX MIS App

510(k) Owner Information

Name:	Orthofix US LLC
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Telephone Number:	214-937-2176
Fax Number:	214-937-3322
Email:	shantaghyarian@orthofix.com
Registration Number:	2183449
Contact Person:	Shant Aghyarian
Date Prepared:	September 21, 2023

Name of Device

Trade Name / Proprietary Name:	OFIX MIS App
Common Name:	OFIX MIS App
Product Code(s):	LLZ
Classification Name:	System, Image Processing, Radiological
Regulatory Class:	Class II per 21 CFR 892.2050
Predicate Devices:	Nemaris Surgimap 2.0, K141669

Device Description

OFIX MIS App

The OFIX MIS App will provide a novel mobile phone solution to supplement the use of calipers when selecting rods used in immobilization and stabilization of pedicle screw type spinal systems. The App will rely on capturing 2D images used in spinal implant procedures through use of mobile phone camera. The App measures the difference between known Orthofix pedicle screw diameters and provides feedback useful in determining appropriate rod length with corresponding Orthofix product number.

Indications for Use

The OFIX MIS App software assists healthcare professionals in viewing, storing, and measuring images as well as planning orthopedic surgeries. The App allows service providers to plan surgical procedures by including tools for measuring anatomical components for placement of surgical implants. Clinical judgment and experience are required to properly use the software.

Technological Comparison

The technological comparison is provided as the Substantial Equivalence table below.

Substantial Equivalence Table

Specification/Property	Predicate Device Nemaris Surgimap 2.0 (K141669)	Subject Device OFIX MIS App	Discussion
Intended Use / Indications for Use	The Surgimap software assists healthcare professionals in viewing, storing, and measuring images as well as planning orthopedic surgeries. The device allows service providers to perform generic as well as specialty measurements of the images, and to plan surgical procedures. The device also includes tools for measuring anatomical components for placement of surgical implants and offer online synchronization of the database with the possibility to share data among Surgimap users. Clinical judgment and experience are required to properly use the software.	The OFIX MIS App software assists healthcare professionals in viewing, storing, and measuring images as well as planning orthopedic surgeries. The app allows service providers to plan surgical procedures by making measurements for the placement of surgical implants. Clinical judgement and experience are required to properly use the software.	The OFIX App doesn't measure anatomical components but helps measure distances on anatomical components between placed markers (pedicle screws). The predicate is more involved in overall pre-operative planning. This could be determinant of the surgical procedure or approach taken by the surgeon. The OFIX MIS App, is a lower risk tool used to streamline the process of measuring and choosing the correct rod to be used in the surgical procedure. The surgical procedure and approach would already be decided at this point. As a safeguard, the surgeon has access to traditional means of measurement such as calipers. This is a check in case the surgeon wants to confirm the OFIX MIS App's measurement.
Device Classification Name	Medical image management and processing system	Medical image management and processing system	Same
Software Functionalities/ Modalities	Generic, Spine, and Lower Limbs Measurements, Pre-op Planning, Templating (vendor specific implants and custom implants), Database, Case Sharing	Templating (vendor specific implants), Database	The OFIX MIS App is a simplified software that is for templating Orthofix specific implants. It is comparable to the predicate in that manner without the additional functionalities that the predicate offers. The predicate has previously been used by medical professionals to template Orthofix implants. After measuring, the OFIX MIS App recommends a rod length pulled from its database. This doesn't not affect the safety and effectiveness of the device and the OFIX MIS App is of lower risk than the predicate.
Algorithms	Osteotomy Module	Orthofix Implants Module (Not machine-learning based)	The OFIX MIS App is a simplified software that is for templating Orthofix specific implants. The algorithm used is not machine learning based and uses information specific to Orthofix implant systems to analyze the captured image (input) and recommend the correct implant (output).
User Interface	PC	Mobile Device	This difference is expanded on more in the 510(k) Summary in which the OFIX MIS App is compared with the Surgimap 2.0 predicate and the Nuvaline reference devices. All the devices are used outside the sterile field and are accessible without impedance (no gloves). Compared the PC interface of Monitor/Keyboard/Mouse, The Mobile Device touch screen provides the same sufficient image handling (moving/zooming in) needed to perform the steps to measure and template the implant. Compared to the predicate, as discussed above, the overall risk is lower for the OFIX MIS App compared to the predicate in terms of its single functionality. The mobile interface makes it more accessible in the intraoperative environment. The safety and effectiveness of the App is demonstrated through user validation and testing, and this difference does not render the OFIX MIS App not substantially equivalent.
Obtaining an image	Transferred from other devices	Mobile Device Camera	This difference is expanded on more in the 510(k) Summary in which the OFIX MIS App is compared with the Surgimap 2.0 predicate and the Nuvaline reference devices. The Nuvaline (K162647) uses a Mobile Device Camera to obtain the image and predicated against the Surgimap 2.0. The use of a Mobile Device Camera to obtain the image has been validated to demonstrate sufficient input to the OFIX MIS App to measure and output an accurate implant length. User validation was performed to ensure safety and effectiveness. This difference does not render the App not substantially equivalent.
DICOM	Yes	N/A	The OFIX MIS App, is a lower risk tool used to streamline the process of choosing the correct rod to be used in the surgical procedure. It processes pictures of a fluoroscopy monitor acquired by a cell phone camera.

Non-Clinical Test Conducted for Determination of Substantial Equivalence

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The testing demonstrated that the App meets the required specifications.

Usability Testing

The OFIX MIS App demonstrated accuracy and usability with bench top and simulated use testing.

Conclusion

The OFIX MIS App is substantially equivalent to the predicate despite the minor technological differences described. The testing data support the safety and effectiveness of the OFIX MIS App and demonstrate performance as intended in the specified use conditions. This performance is comparable to the predicate's respective software functionality.