FH Industrie
℅ Dawn Norman
Partner
MRC Global, LLC
9085 E. Mineral Circle, Suite 110
CENTENNIAL CO 80112

September 30, 2022

Re: K220758
Trade/Device Name: e-Ortho Shoulder Software v1.1
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: July 29, 2022
Received: August 1, 2022

Dear Dawn Norman:

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.

510(k) Number *(if known)*
K220758

Device Name
e-Ortho Shoulder Software v1.1

Indications for Use *(Describe)*
E-Ortho shoulder is intended to be used as an information tool to assist in the preoperative surgical planning and visualization of a primary total shoulder replacement.

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
FH Industrie e-Ortho Shoulder Software v1.1
September 30, 2022

Company: FH INDUSTRIE
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QUIMPER Finistere, FRANCE 29000

Company Contact: Oscar Ramirez -- FH Industrie

Official Correspondent: Dawn Norman – MRC Global, LLC

Trade Name: e-Ortho Shoulder Software v1.1

Common Name: System, Image Processing, Radiological

Classification: Class II

Regulation Number: 21 CFR 892.2050 (Picture archiving and communications system)

Panel: Radiology

Product Code: LLZ

Predicate Device: FH Industrie – e-Ortho Shoulder – K201928

Device Description:
e-Ortho Shoulder software is a web-based surgical planning software application. e-Ortho Shoulder provides a pre-surgical planning tool for surgeons that helps them understand their patient's anatomy prior to surgery. Compared to using two-dimensional (2D) images to plan a shoulder arthroplasty (current method used by FH-Orthopedic surgeons), e-Ortho supplies information to surgeons to help prepare an intraoperative plan. E-Ortho allows surgeons to work in three-dimensional (3D) visualization, implant visualization and positioning within the specific patient's bone model (scapula and humerus), using reliable landmarks. This allows surgeons to preoperatively select the needed implant and determine its desired position.

The subject submission seeks to add humeral planning capabilities to the previously cleared FH E-Ortho Shoulder Software. Additional changes to the software have been made to improve functionality within the previously cleared intended use.

Indications for Use:
E-Ortho shoulder is intended to be used as an information tool to assist in the preoperative surgical planning and visualization of a primary total shoulder replacement.

Substantial Equivalence:

The subject e-Ortho shoulder software is substantially equivalent to the following predicate:

FH Industrie – e-Ortho Shoulder – K201928

The subject e-Ortho Shoulder software is similar to the predicate with respect to intended use, indications for use, technological characteristics, and principles of operation. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Table 1: Comparison of Subject and Predicate Devices

Device	**SUBJECT DEVICE**	**PREDICATE DEVICE**
Name	**e-Ortho Shoulder Software (V1.1)**	**e-Ortho Shoulder Software (V1.0)**
Company	**FH Industrie**	**FH Industrie**
510k Clearance		K201928
Product Code	LLZ	LLZ
Indications for Use	Identical. E-Ortho shoulder is intended to be used as an information tool to assist in the preoperative surgical planning and visualization of a primary total shoulder replacement.	E-Ortho shoulder is intended to be used as an information tool to assist in the preoperative surgical planning and visualization of a primary total shoulder replacement.
User Poplulation	Identical. Orthopedic Surgeon	Orthopedic Surgeon
Principles of Operation	Identical. Software system with a user interface that provides surgeons with analysis tools to input, review, and assess fluoroscopic images to assist in implant selection and placement during total shoulder replacement procedures.	Software system with a user interface that provides surgeons with analysis tools to input, review, and assess fluoroscopic images to assist in implant selection and placement during total shoulder replacement procedures.
Operating System	Identical. Mac OS 10.13 or higher and Windows 8 or higher	Mac OS 10.13 or higher and Windows 8 or higher
Image Data	Identical. CT Scan per protocol	CT Scan per protocol
Features	Identical with the following additions: • added metrics (Elbow version angle (if landmarks contain an elbow axis), Native roll, Angle of glenoid version and inclination for native	<u>Pre-operatively</u>: • Helps a surgeon better understand patient-specific anatomy prior to surgery • Provides surgeon three-dimensional (3D) visualization in of implant placement prior to surgery, allowing for the following:

Device	SUBJECT DEVICE	PREDICATE DEVICE
	glenoid displayed on 2D views, and Optional extra axis version & inclination) • inclusion of more information to be provided about the surgeon and the patient • new rendering mode displays, • new optional model visualization • minor display improvements • Expanded correction range to support an extra surgical technique planning (double reaming) if required • inclusion of a free planning mode where user can select any value of glenoid correction, in a predefined range • Improved keel perforation detection and its visualization • Improved prosthesis translation by sliding and rolling the implant into the selected glenoid sphere surface • Ability to compute, display, and adjust glenoid graft (3D rendering Width, Height, Thickness max). • Adapt planning reference surface to support an extra category of glenoid deformities (bi-concavity) deformity. Added ability to activate and select sphere surface reference in case of bi-concavity (Paleo-glen or Neo-glen). "Relative" angles and reference sphere surface for translating the glenoid implant are based on the selected sphere. • Ability to visualize shoulder offset distances (lateralization…) if reduced joint page has been visited. • Improved screw perforation detection by adding more perforation landmarks • Improved GUI texts. Improve Warnings texts.	○ more appropriate implant selection and sizing. ○ Possible prevention of unintended perforations and complications due to selection of the incorrect implant or screw sizes ○ Better prediction of the optimal option for implant positioning and screw placement • Pre-operative, three-dimensional visualization provides landmarks to the surgeon for better pre-surgical preparation and planning • Separate screens for each phase of planning: review of patient anatomy, glenoid placement planning, and screw placement planning. • Subluxation visualization in 2D and 3D

Performance Testing:

In order to ensure the performance of the e-Ortho throughout the project's development, a verification and validation process has been established and conducted per IEC 62304. The verification process was implemented through five test campaigns and was carried out by five different evaluators in two different environments to verify the functional components of the subject device. Three bugs were identified as remaining problems after the debugging campaign; however, all are minor and not expected to impact the planning itself.. The validation process was implemented through a usability test campaign, with critical features requiring validation by five surgeons. The result of the validation tests coincides with the expected results for each test case and no test failed. Similar to the predicate device, additional accuracy testing was carried out to guarantee the performance of e-Ortho as follows: the

sequence of events which could lead to dangerous situations and potential harms were identified then simulated in different virtual cases including right and left sided scenarios in head-first supine positioning of patient as well as feet-first supine patient positioning, varying reaming depths, and implant visualization from varying angles. These simulations were carried out using the subject device, compared to the "gold standard" Materialise innovation Suite (Mimics V 22 and 3matic V 14) and SolidWork 2016 for implant values (version and inclination). All tests passed. Thus, the accuracy of e-Ortho is adequate to provide safe use of the product.

*Note: e-Ortho shoulder is intended to be used only with the following previously cleared FH Orthopedic implants: Arrow Anatomical shoulder prostheses (K093599, K162068), Arrow Reverse shoulder prostheses (K112193, K142778, K171789).

Conclusion

The e-Ortho Shoulder software v1.1 is shown to be substantially equivalent to its predicate/previously cleared version, e-Ortho Shoulder Software (K201928). The subject software has similar intended uses, indications, technological characteristics, and principles of operation as its predicate device. The minor differences do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, performance data demonstrate that e-Ortho raises no new questions of safety or effectiveness. Thus, the updated e-Ortho Shoulder software is substantially equivalent to the previously cleared version.