FH Industrie
% Ms. Dawn Norman
Exec VP
MRC Global, LLC
9085 East Mineral Circle, Suite 110
CENTENNIAL CO 80112

September 30, 2020

Re: K201928
Trade/Device Name: e-Ortho Shoulder Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: July 9, 2020
Received: July 14, 2020

Dear Ms. 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201928

Device Name
e-Ortho Shoulder Software

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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K201928

510(k) Summary

FH Industrie e-Ortho Shoulder Software

September 9, 2020

Company: FH INDUSTRIE
ZI DE KERNEVEZ-6 RUE NOBEL
QUIMPER Finistere, FRANCE 29000

Company Contact: Oscar Ramirez -- FH Industrie

Official Correspondent: Dawn Norman – MRC Global, LLC

Trade Name: e-Ortho Shoulder Software

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

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.

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:

JointPoint, Inc. JointPoint – K160284

Both the subject and predicate devices are image processing softwares intended to aid in planning and positioning orthopedic components during orthopedic surgical procedures by using radiographic imaging to map anatomic landmarks and dimensions. However, the major differences between the subject and predicate device are that the subject e-Ortho software is only intended to be use before surgery as a pre-planning tool, while the predicate JointPoint covers a broader range of the surgical workflow. However, the indications for use for the predicate fully encompass the indications for use of e-Ortho Shoulder software. Therefore, this difference does not alter the intended use or otherwise raise new questions compared to the predicate. Additionally, the subject e-Ortho Shoulder software is specific in its indication for arthroscopic total shoulder replacement procedures, while the predicate device is specific to total hip replacement, total knee replacement, and intertrochanteric fracture reduction procedures . However, this minor difference in anatomical location does not alter the intended use of the device and thus, does not raise new questions of safety or effectiveness.

Both the subject and predicate softwares include software prediction of optimal implant sizing as a preoperative planning tool. While e-Ortho's software will be used to provide implant sizing and selection recommendations to the surgeon, the inputs of these recommendations are not generated by the software like JointPoint. Rather, the analysis of the patient CT Scans are performed by an e-Ortho engineer after CT scans are uploaded by the surgeon. The surgeon is then able to virtually visualize potential placement implants but using landmarks populated into the e-Ortho software by the e-Ortho engineer, enabling the surgeon to choose the optimal implant type, sizing, and position. All implant selection and sizing options are specific to previously cleared FH Orthopedic shoulder implants and sizes from the FH Orthopedic Arrow Anatomic and Arrow Reverse shoulder systems. While an e-Ortho engineer provides inputs via the e-Ortho software, the chosen procedure is the responsibility of the Surgeon. Prior to any shoulder surgery, the surgeon should evaluate and validate the appropriateness of the procedure to the specific patient based on his/her medical training.

As discussed above, 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.

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 multiple test campaigns and was carried out by various evaluators and environments to verify the functional components of the subject device. The validation process was implemented through a usability test campaign, with critical features requiring validation by multiple surgeons. The result of the validation tests coincides with the expected results for each test case and no test failed. Additional accuracy testing was carried out to guarantee the performance of e-Ortho.

Conclusion

The e-Ortho Shoulder software is shown to be substantially equivalent to its predicate, JointPoint. The subject software has similar intended uses, indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications 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 e-Ortho Shoulder software is substantially equivalent.