Pixee Medical
℅ Agathe Joet
Quality & Regulatory Affairs Engineer
18 rue Alain Savary
Besancon, 25000
FRANCE

July 22, 2022

Re: K213922
Trade/Device Name: FX SPS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 15, 2022
Received: June 21, 2022

Dear Agathe Joet:

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 and Part 809); 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)*

K213922

Device Name

FX SPS

Indications for Use *(Describe)*

FX SPS 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

Pixee Medical's FX SPS

510(k) Submitter:

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Contact Person: Agathe JOËT

Date Prepared: **July 20, 2022**

Device:

Trade name: **FX SPS**
Common name: **Planning software for Total Shoulder Arthroplasty**
Classification name: **System, Image Processing, Radiological (21 CFR §892.2050)**
Product code: **LLZ**
Regulatory class: **II**
Classification Panel: **Radiology**

Predicate Device:

FX SPS is substantially equivalent to the legally marketed e-ortho Shoulder Software.

Applicant Name	Device Name	Product code	510(k) number
FH INDUSTRIE	e-Ortho Shoulder Software	LLZ	K201928

No reference devices were used in this submission.

Device Description:

FX SPS is a preoperative standalone web-based medical software used for the planning of primary shoulder replacement from CT-images. It comprises a secure database which enables the patient's cases management and the access to the planning interface.

Preliminary to the planning, a manual segmentation needs to be performed from the patient's CT-images. The segmentation process consists in building 3D bone models of the patient's shoulder and positioning anatomic landmarks on it. Once these data are generated, their compliance is checked. They are then imported into the FX SPS's database making the planning available for the surgeon.

The planning step involves virtually positioning of the shoulder prosthesis on the 3D reconstruction of the patient's shoulder. On that purpose, the surgeon chooses implants from a library of implants.

Afterwards, he selects the size of the implant more suitable to the joint and he can move prosthesis components in all directions. Once the positioning of the implant is satisfying, he validates the planning to generate a planning report.

During surgery, he will have at its disposal the planning report comprising preoperative and planned parameters.

Intended use / Indications for Use:

FX SPS 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:

- **Comparison of Intended Use / Indications for Use:**

FX SPS and the e-Ortho Shoulder Software are both web-based software indicated for primary total shoulder arthroplasty. Both devices are intended to be used as an information tool to assist in the preoperative surgical planning and visualization of a primary Total Shoulder Replacement. Thus, there is no difference between the subject device and the predicate device with respect to indications and intended use.

- **Comparison of Operating principle**

They both use CT-images of patients to reconstruct 3D models of the shoulder joint and to position anatomical landmarks through a manual segmentation process. In addition, they both allow the surgeons to perform a preoperative planning by enabling reverse and anatomical implant visualization and positioning within the specific patient's bone models. Furthermore, both devices compute and display pre-operative parameters. Both devices generate a downloadable planning report. Thus, FX SPS and E-ortho have the same principle of operation.

- **Comparison of technological characteristics with the predicate device:**

  At a high level, the subject and predicate devices are based on the following same technological elements:

  - Both are web-based software used pre-operatively;
  - Both use CT-scan images;
  - Both integrate anatomic and reverse shoulder implants;
  - Both rely on manual segmentation for 3D models reconstruction;
  - Both function with user profiles determining the possible user's actions;
  - Both manage the cases from a list of patients;
  - Both provide to the user a milling tool;

- Both integrate 3D and 2D representation of the humerus and the scapula.

The following technological difference exists between the subject and predicate devices:

- E-ortho provides software prediction of optimal implant sizing while FX SPS does not.

Discussion regarding the technological characteristics:

Technological characteristics	FX SPS (Device subject of this application)	E-Ortho Shoulder Software K201928 (Predicate device)	Discussion
Type of software	Web-based software	Web-based software	Identical
Use time	Pre-operatively	Pre-operatively	Identical
Imaging used	CT-scan images	CT-scan images	Identical
Type of implants planned	Anatomical and reverse shoulder implants	Anatomical and reverse shoulder implants	Identical
Manual/automatic segmentation	Manual segmentation performed.	Manual segmentation performed	Identical
User profiles	User profiles define the authorized actions for the user.	User profiles define the authorized actions for the user.	Identical
Case management	List of cases	List of cases	Identical
Tools	Milling tool	Milling tool	Identical
Anatomy representation	3D and 2D representation of the humerus and the scapula.	3D and 2D representation of the humerus and the scapula.	Identical
Recommandations	Does not include any predictions and recommendations.	Include software prediction of optimal implant sizing.	While the E-ortho software includes prediction of optimal implant sizing, FX SPS does not. Yes, it makes FX SPS less critical regarding to the safety, as the surgeon's planning is not influenced

The minor difference in technological characteristics between the subject device and the predicate does not alter the intended use of the device and does not raise new questions of safety nor effectiveness.

Non-Clinical Performance Data:

The following testing was conducted to evaluate the device:

- Software verification and validation testing were conducted as required by IEC 62304 and documentation was provided as recommended by the FDA Guidance "Content of Premarket Submissions for Software Contained in Medical Devices". The FX SPS software was considered as a software with a "moderate" level of concern. All performance testing demonstrated that FX SPS performs according to its specifications and functions as intended.
- Concerning the angle or gap measurements, software verification and validation testing were conducted. All performance testing demonstrated that FX SPS performs according to its specifications and functions as intended to ensure the required angle accuracy of 1 degree and gap measurement accuracy of 1 mm.
- User needs validation - The software was validated with intended users through a human factor test series to ensure the user needs and intended use requirements were met, in accordance with IEC 62366-1. All requirements were met and no new issues of safety or effectiveness were raised.

Therefore, the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

Conclusion:

FX SPS has the same intended use, indications and principle of operation as its predicate device, as well as similar technological characteristics. The minor differences in technological characteristics do not alter the intended use of the device and do not raise new questions of safety and effectiveness, and performance data demonstrated that FX SPS is as safe and effective as the E-ortho shoulder software. Thus, the FX SPS software is substantially equivalent to the legally marketed predicate device.