September 1, 2022

Pixee Medical
Lucie Pecheur
Regulatory Engineer
18 rue Alain Savary
Besançon, 25000
France

Re: K220104
Trade/Device Name: Knee+
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 29, 2022
Received: August 1, 2022

Dear Lucie Pecheur:

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: Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
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 on last page

510(k) Number *(if known)*

K220104

Device Name

Knee+

Indications for Use *(Describe)*

Knee+ is a stereotaxic system including an intraoperative software as a medical device and surgical instruments. Knee+ is intended for primary Total Knee Replacement, to assist the surgeon in determining reference alignment axes in relation to anatomical landmarks, in order to position the cutting guide regarding computed mechanical axis. The Knee+ includes smart glasses as a Head Mounted Device (HMD) for displaying information to the user intraoperatively. The smart glasses should not be relied upon solely and should always be used in conjunction with traditional methods.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human
Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

510(k) Submitter:

Name: Pixee Medical
Address: 18 rue Alain Savary
25000 Besançon
FRANCE

Phone: (+33) 4 58 10 13 65
Fax: (+33) 4 58 10 14 51

Contact Person: Lucie Pecheur

Date Prepared: July 29, 2022

Device:

Trade name: **Knee+**
Common name: **Surgical Navigation Software and Instruments**
Classification name: **Orthopedic Stereotaxic Instrument (21 CFR §882.4560)**
Product code: **OLO**
Regulatory class: **II**
Classification Panel: **Orthopedic**

Predicate Device:

Knee+ is substantially equivalent to the previous version of Knee+, legally marketed:

Applicant Name	Device Name	Product code	510(k) number
Pixee Medical	Knee+	OLO	K202750

No reference devices were used in this submission.

Device Description:

The main purpose of Knee+ is to assist the surgeon during the primary Total Knee Replacement (TKR) intervention. Knee+ includes software and surgical instruments.

Knee+ provides information to help locate and orientate the main femoral and tibial cutting planes as required in knee replacement surgery. Knee+ allows the surgeon to adjust the cutting plane orientation and the resection level. This includes means for the surgeon to collect anatomical references during the TKR intervention using the surgical instruments. The software locates in a 3D reference frame the instruments which include markers. All collected coordinates are treated by software algorithms to provide the surgeon with relevant orientation of the tracked cutting guide. Knee+ software is installed on a wearable Head Mounted Device (HMD) which includes an embedded camera and displays intraoperative information to the user. This near-eye display allows the surgeon to look at the HMD screen or the field of view when needed.

Intended Use / Indications for Use:

Knee+ is a stereotaxic system including an intraoperative software as a medical device and surgical instruments. Knee+ is intended for primary Total Knee Replacement, to assist the surgeon in determining reference alignment axes in relation to anatomical landmarks, in order to position the cutting guide regarding computed mechanical axis. The Knee+ includes smart glasses as a Head Mounted Device (HMD) for displaying information to the user intraoperatively. The smart glasses should not be relied upon solely and should always be used in conjunction with traditional methods.

Summary of Technological Characteristics:

The subject Knee+ device is identical to the most recent clearance (K202750) with the exception of additional alternative instruments and the add-on software component intended to be used before launching the software medical device.

The subject Knee+ device and its predicate device have the same indications for use: they are both stereotaxic systems indicated for primary Total Knee Replacement. They both include surgical instruments and software installed into a Head Mounted Device for displaying information to the user intraoperatively. The subject Knee+ device and its predicate device both assist the surgeon in determining reference alignment axes in relation to anatomical landmarks, in order to position the cutting guide regarding computed mechanical axis.

Both systems include bone references to allow tracking of the tibia and femur. As its previous version, Knee+ defines the femoral mechanical axis as the axis between the hip center (femoral head center) and the knee center (distal femoral center). As its predicate, Knee+ defines the tibial mechanical axis as the axis between the knee center (tibial spines center) and the ankle center (the middle of the two malleoli). Both systems provide cut orientation and resection level to the user. In both systems, the orientation of the distal and proximal cuts in both longitudinal and frontal planes are respectively computed relative to the femoral mechanical axis and the tibial mechanical axis.

The main differences with the predicate are:

- The addition of new instruments to complete the range of Knee+ instruments available for users. These new instruments are very similar to the instruments already cleared in K202750 and follow the same principle of operation.
- The addition of a software component, also installed on the Head Mounted Device (HMD), which allows the user to scan QR-codes in order to access to optional settings (demo mode, duplication of HMD display, languages, …), to manage instrument configuration and reload tokens.

The operating principle, the surgical workflow, the environment of use and the main system component remain the same as the predicate device (K202750). The tracking system technology, the use of a Head Mounted Device to provide information and the claimed accuracy for cut orientation and resection level also remain the same as the most recent cleared version (K202750).

The information provided by Pixee Medical in this 510(k) application demonstrated that Knee+ is substantially equivalent to its predicate device as the minor differences do not raise any concerns regarding the safety and effectiveness of the device.

Non-Clinical Performance Data:

As the most recent clearance (K202750), the following testing was conducted to evaluate the Knee+ device, subject of this premarket submission:

- Bench testing was conducted in order to demonstrate that Knee+ performs according to its requirements and specifications when installed on the Head Mounted Device. In particular, overall system repeatability and accuracy were tested.

- Software verification and validation testing were conducted as required by IEC 62304 and documentation was provided as recommended by FDA Guidance “Content of Premarket Submissions for Software Contained in Medical Devices”.

- Functional and performance tests have been performed on the instruments to provide confirmation that mechanical instrumentation satisfies functional and performance requirements.

- Cleaning and sterilization process of the reusable instruments was validated to SAL 10^{-6}. Validation was performed in accordance with AAMI TIR30 guidance, and for steam sterilization, in compliance with the half-cycle validation approach outlined in ISO 17665-1, in accordance with the requirements of ISO 17664 and FDA guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling”.

- Biocompatibility of the instruments was performed. Testing was done according to ISO 10993 series. All tests were successfully completed for patient contact materials.

- Human factors data were provided, in compliance with the requirements of IEC 62366-1 and FDA guidance “Applying Human factors and usability engineering to medical devices”. Test participants representing the intended users of the device were included in the human factor validation testing. Observational data as well as interview data were recorded. The observation of participant performance and the assessment of their understanding of essential information through the interview confirmed that the design of the device, including the additional features of the latest version, is safe and effective for the intended users, uses and use environments.

All performance testing demonstrates that Knee+ performs according to its specifications and functions as intended.

Conclusion:

Knee+ has the same intended use, indications for use, principle of operation and technological characteristics as its predicate device (i.e., the most recent cleared version K202750). The addition of alternative instruments and software component do not alter the intended surgical use of the device and do not raise new questions of safety and effectiveness. Performance data demonstrated that Knee+ is as safe and effective as its previous version. Thus, the Knee+ is substantially equivalent to the legally marketed predicate device.