April 21, 2023

Pixee Medical
Lucie Pécheur
Regulatory Affairs Manager
14 rue Alain Savary
Besancon, 25000
France

Re: K230789
Trade/Device Name: Knee+
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 17, 2023
Received: March 22, 2023

Dear Lucie Pécheur:

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,

Shumaya Ali -S

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 below.

510(k) Number *(if known)*
K230789

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.

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510(k) SUMMARY

Pixee Medical's Knee+

510(k) Submitter:

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FRANCE

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Contact Person: Lucie Pecheur

Date Prepared: March 17, 2023

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	K220104

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 a camera

and displays intraoperative information to the user. A 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 device subject of this Premarket Notification is a modification from the device legally authorized under K220104, also manufactured by Pixee Medical.

There are no differences between the subject device and the predicate (previous version of the device) with respect to indications and intended use.

The main change from the previous version (K220104) is the addition of an external camera to the Head-Mounted Device (HMD) in order to use Knee+ device underneath surgical helmets.

Consequently, the installation of the Head Mounted Device under the surgical helmet is a new step of the usage workflow. Nevertheless, this step is performed before starting the surgery, and the successive steps of the surgical workflow remain the same as the cleared K220104. The information is still provided to the user through the near-eye display of the Head-Mounted Device.

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 (K220104).

The main change as well as other minor changes were assessed through risk management activities, including relevant verification and validation information, produced under design controls procedures. The results of the design controls activities were provided as a summary in the Premarket Notification.

Substantial equivalence was therefore supported by performance data which demonstrated that the modified Knee+ device is still safe and effective for its intended use. The differences from the previous version do not raise any concerns regarding the safety and effectiveness of the device.

Non-Clinical Performance Data:

Performance data were necessary to demonstrate that the same performance is still achieved with the use of the external camera, under a surgical helmet. The same methods, protocols and acceptance criteria used to support the previously cleared K220104 were applied to evaluate the change, as well as FDA-recognized standards methods (well-established methods):

- Bench testing was conducted in order to demonstrate that Knee+ performs according to its requirements and specifications when installed on the Head Mounted Device under a surgical helmet. In particular, repeatability and accuracy were tested according to ASTM F2554.

- User needs validation - The system was validated in accordance with IEC 62366-1 by the intended users to ensure that the installation of the modified Head-Mounted Device and the user underneath surgical helmets do not raise new issues of safety or effectiveness.

- 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”.

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 and technological characteristics as its predicate device (i.e., the most recent cleared version K220104). The addition of an external camera to the Head-Mounted Device and other minor modifications 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, also manufactured by Pixee Medical. Thus, the Knee+ is substantially equivalent to the legally marketed predicate device.