April 21, 2021

Pixee Medical
Lucie Pecheur
Quality & Regulatory Affairs Engineer
18 rue Alain Savary
Besancon, 25000
France

Re: K202750
Trade/Device Name: Knee+
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 19, 2021
Received: March 22, 2021

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202750

Device Name

Knee+

Indications for Use *(Describe)*

Knee+ is a stereotaxic system including a dedicated intraoperative standalone software 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

Phone: (+33) 4 58 10 13 65
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Contact Person: Lucie Pecheur

Date Prepared: March 10, 2021

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 Devices:

Primary predicate device:

- Navitrack® System - OS Knee Universal, K110054, product code OLO, Zimmer CAS

Additional predicate device:

- xvision Spine, K190929, product code OLO, Augmedics Ltd.

Device Description:

The main purpose of Knee+ is to assist the surgeon during the primary Total Knee Replacement (TKR) intervention. Knee+ includes KneePlus software and reusable KneeTools 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 KneeTools instruments. KneePlus software locates in a 3D reference frame the KneeTools instruments which include markers. All collected coordinates are treated by KneePlus algorithms to provide to the surgeon relevant orientation of the tracked cutting guide.

The KneePlus software is installed on a monocular near-eye HMD and provides the field of vision of the embedded HMD camera with additional information on an opaque 2D OLED screen. The surgeon uses this near-eye display in a very similar way he uses a traditional monitor such as the primary predicate device (Navitrack® System - OS Knee Universal, K110054): the surgeon can choose to look at the screen only when needed. The near-eye display is similar to what would be displayed on the screen of a tablet, smart phone or laptop positioned on a table next to the user.

Intended Use / Indications for Use:

Knee^{+} is a stereotaxic system including a dedicated intraoperative standalone software 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.

Comparison of Technological Characteristics:

Knee^{+} and Navitrack® System - OS Knee Universal are both stereotaxic devices, indicated for Total Knee Replacement to assist the surgeon in the positioning of orthopedic components intra-operatively. Both devices are intended to assist the surgeon in determining reference alignment axes in relation to anatomical landmarks, in order to position alignment instruments regarding computed mechanical axis.

Both Knee^{+} and Navitrack® System – OS Knee Universal involve several components, such as a software and reusable instruments, including tracking components to provide positional information to help orient and locate the main femoral distal and tibial proximal cutting planes as required in knee replacement surgery. The femur and tibia are displayed to the user in the form of their mechanical alignment axis. In both Knee^{+} and Navitrack® System – OS Knee Universal, the alignment axes are determined and recorded intra-operatively by identifying the key anatomical references that are used clinically to align and position the total knee implants.

Both systems include bone references to allow tracking of the tibia and femur. As its predicate, 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 relatively to the femoral mechanical axis and the tibial mechanical axis.

The subject device (Knee+) and the primary predicate device (Navitrack® System - OS Knee Universal, K110054) share the following characteristics:

- Intended use / Indications for use;
- Principle of operation;
- Surgical workflow;
- Environment of use;
- Main system components;
- Use of surgical instruments for navigation with markers;
- Intraoperative use;
- Orientation and positioning of bone resections;
- Device accuracy.

The main differences with respect to the predicate concerns:

- the tracking system technology (visible image vs. infrared), and
- the use of a Head Mounted Device (instead of a screen on a workstation) to provide information to the surgeon.

Where Knee+ tracking system relies on visible image technology, Navitrack® - OS Knee Universal tracking system relies on infrared technology. Even though differences in technology can be noticed between the predicate device and Knee+, a comparison study between Knee+ and Navitrack® - OS Knee Universal (bench testing and cadaveric testing) confirmed that the subject device and its primary predicate have the same accuracy.

The use of a Head Mounted Device (HMD) for displaying information to the user intraoperatively is not a new feature and has been previously cleared under K190929 for the xvision Spine system (secondary predicate device).

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

Non-Clinical Performance Data:

The following testing was conducted to evaluate the device:

- Bench testing was conducted in order to demonstrate that KneePlus software performs according to its requirements and specifications. In particular, overall system repeatability and accuracy were tested.

- Performance comparison studies have been performed between Pixee Medical's device and the primary predicate device (Navitrack® System - OS Knee Universal) on test bench (sawbones) and simulated use (cadaveric specimens with orthopedic surgeon). The aim was to compare the accuracy of both systems and therefore assess the performance of Knee+.

- User needs validation - The system was validated with intended users in cadaver studies and simulated use tests 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.

- 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”. The software for this device was considered as a “moderate” level of concern.

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

- Cleaning and sterilization process of the reusable KneeTools 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 KneeTools instruments was performed. Testing was done according to ISO 10993 series. All tests were successfully completed for patient contact materials.

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

Conclusion:

Knee^{+} has the same intended use and similar indications, and principle of operation as its primary predicate device. The minor differences in technological characteristics do not alter the intended surgical use of the device and do not raise new questions of safety and effectiveness, and performance data demonstrated that Knee^{+} is as safe and effective as the Navitrack® System - OS Knee Universal. The use of a wearable head-mounted device for displaying information to the user intraoperatively has been previously cleared under K190929 for the xvision Spine, used as a secondary predicate. Thus, the Knee^{+} is substantially equivalent to the legally marketed predicate devices.