March 20, 2025

Pixee Medical
François Beaumont
Regulatory Affairs engineer
18 rue Alain Savary
Besançon, 25000
France

Re: K243975
Trade/Device Name: Knee+
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: SBF
Dated: December 20, 2024
Received: December 23, 2024

Dear François Beaumont:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243975

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.

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510(k) #: K243975

510(k) Summary

Prepared on: 2025-01-24

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Pixee Medical
Applicant Address	18 rue Alain Savary Besançon 25000 France
Applicant Contact Telephone	+33458101365
Applicant Contact	Mr. François BEAUMONT
Applicant Contact Email	francois.beaumont@pixee-medical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Knee+
Common Name	Stereotaxic instrument
Classification Name	Orthopedic Augmented Reality
Regulation Number	882.4560
Product Code(s)	SBF

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233899	Knee+	OLO

Device Description Summary

21 CFR 807.92(a)(4)

Knee+ is a navigation system dedicated to orthopaedic knee surgery. It includes KneePlus software and KneeTools reusable surgical instruments.
The main purpose of Knee+ is to assist the surgeon during primary Total Knee Arthroplasty (TKA) interventions.
Knee+ provides information to help locate and orientate the main femoral and tibial cutting planes as required during TKA. Knee+ allows the surgeon to adjust the orientation of the cutting plane orientation and the level of resection by collecting anatomical references during the TKA procedure using 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 and location of the tracked cutting guide. Knee+ software is installed on a wearable Head Mounted Device (HMD) which includes a camera, a computer and displays intraoperative information to the user. A near-eye display allows the surgeon to look at the HMD screen when needed.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

There is no difference between Knee+ and the predicate device with respect to indications and intended use as the intended purpose as

well as clinical performances and benefits have not been modified compared to its previous version. Precision and accuracy of the device remain unchanged compared to previous version when measured according to the same methods.

Technological Comparison

21 CFR 807.92(a)(6)

The device subject of this Premarket Notification is a modification from the device legally authorized under K233899, also manufactured by Pixee Medical.
Knee+ is substantially equivalent to its previous version cleared under K233899 with the main modifications being:
- the reintroduction of the possibility to perform mechanical resection level measurement as it was possible in previous version K220104,
- the modification of two instruments (Orientation mechanism and Cutting guide adaptor from K233899 including the addition of a new material and a new anodization process for the wheels),
- the addition of voice command as an optional alternative to button selection through accelerometer,
- the possibility to optionally connect the device to a connectivity module,
- the addition of a user profile and its associated information (protocol preferences, surgery cases),
- the redesign of the visual interface
- the modification of the hip center acquisition constraint (from 10 to 5 acquisitions needed)
- Flyte surgical helmet (K060713) compatibility replaced by compatibility of Knee+ with a new reference of surgical helmet and hoods available in the operating room (K200493 Stryker T7)

The main changes 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 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 and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following testing was conducted to evaluate the Knee+ device, subject of this premarket submission, in order to confirm that Knee+ performs as intended and is as safe as its previously marketed version (K233899):
- Bench testing was conducted in order to demonstrate that Knee+ performs according to its requirements and specifications. In particular, repeatability and accuracy were tested according to ASTM F2554.
- 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.
- 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 Device Software Functions".
- Cleaning and sterilization process of the reusable instruments was validated to SAL 10-6. Validation was performed in accordance with AAMI ST98 and AAMI TIR12 guidances, and for steam sterilization, in compliance with the half-cycle validation approach outlined in ISO 17665-1, in accordance with the requirements of ISO 17664-1 and FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling".
- Biocompatibility testing (cytotoxicity, sensitisation, pyrogenicity, acute systemic toxicity and irritation) have been performed according to ISO 10993 standard series following instrument modification and confirmed that the patient-contacting materials do not introduce new risks and that the KneeTools instruments were safe and biocompatible.
All performance testing demonstrates that Knee+ performs according to its specifications and functions as intended.

Clinical testing is not applicable.

Knee+ has the same intended use and indications for use that its predicate device (i.e., the most recent cleared version K233899). The prior mentioned modifications do not raise new questions on safety and effectiveness as non-clinical testing performed demonstrated the performance of the device were unchanged and substantially equivalent to its predicate (K233899).