April 24, 2026

Pixee Medical S.A.S.
François Beaumont
Regulatory Affairs Engineer
18 Rue Alain Savary
Besançon, 25000
France

Re: K253805
Trade/Device Name: Knee+
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: SBF
Dated: March 26, 2026
Received: March 26, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253805

Please provide the device trade name(s).

Knee+

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
- ☐ Infants (29 days old to < 2 years old)
- ☐ Children (2 years old to < 12 years old)
- ☐ Adolescents (12 years old to < 22 years old)
- ☒ Adults (22 years old and greater)

K253805 510(k) SUMMARY
Pixee Medical - KNEE+

510(k) Submitter:

Name: Pixee Medical

Address: 18 rue Alain Savary

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France

Phone: (+33) 4 58 10 13 65

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Date Prepared: March 25th, 2026

Device:

K253805

Trade name: Knee+

Common name: Surgical Navigation Software and Instruments

Classification name: Orthopedic Augmented Reality (21 CFR §882.4560)

Product code: SBF

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+	SBF	K243975

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 K243975, also manufactured by Pixee Medical.

There are no differences between the subject device and the predicate with respect to indications and intended use.

The main change from the previous version (K243975) is the addition of a qualified execution platform compatible with the KneePlus software.

The previous qualified execution platform had 4 components while the new one has only two (smart glasses with integrated camera and external battery).

The surgical protocol and the technics to determine and display the pose of the instruments are identical to the predicate 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 (K243975).

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 concern regarding the safety and effectiveness of the device.

Nonclinical Performance Data:

Performance data were necessary to demonstrate that the same performance is still achieved with the use of the new qualified execution platform. The same methods, protocols and acceptance criteria

used to support the previously cleared K243975 were applied to evaluate the change, as well as FDA-recognized standards methods:

- Bench testing was conducted in order to demonstrate that Knee+ performs according to its requirements and specifications and use conditions. In particular, repeatability and accuracy were tested according to ASTM F2554.

- User needs validation – The system was validated in accordance with IEC 62366-1 and FDA guidance "Applying Human factors and usability engineering to medical devices". A human factor validation study was conducted with 15 surgeons with different types of experiences performing the complete Knee+ workflow up to completion of the guided bone resections in a representative operating room environment (sawbones, surgeon positioning, wearable platform worn under surgical helmet or without) insuring the coverage of all surgeon's device usages through the entire surgery. The purpose of this evaluation was to determine whether the new execution platform affects human factor validation.

- 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".

- EMC and electrical safety testing have been performed on the qualified execution platform in accordance with IEC 60601-1, IEC 60601-1-2, EN 62368-1, the ETSI EN 301 489 series, and other applicable standards.

- Biocompatibility assessment has been performed according to ISO 10993 standard following instrument modification and confirmed that the patient-contacting materials do not introduce new risks and that the Knee Tools instruments were safe and biocompatible.

- Quantitative Cadaver Validation - A study was conducted using three surgeons and involving 9 knees conducted in a clinically simulated setting using cadaver specimens.
The objectives of this study was to:
• Observe device utilization in a clinically simulated setting using cadaver specimens,
• Compare performance between the device under evaluation and its predicate device,
• Collect complementary data: observations or recommendations.

In parallel to the procedure performed by the surgeon, an operator wore the predicate device. The data collected of the new augmented reality device was then compared to the predicate.

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 K243975). The addition of a qualified execution platform and other minor resulting 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.