Pixee Medical announces FDA 510(k) clearance for its next-generation solution, Knee+ NexSight, on a new Augmented Reality platform.

April 2026 – Besançon, France – Pixee Medical, a pioneer in Augmented Reality (AR) navigation for orthopedic surgery, today announced that it has received FDA 510(k) clearance for Knee+ NexSight, developed on a new AR platform for total knee arthroplasty (TKA).

This new clearance enables Pixee Medical to address the growing U.S. market, with a focus on ambulatory surgical centers (ASCs), where efficiency, simplicity, and cost control are key drivers. Knee+ NexSight has been designed to integrate seamlessly into these high-demand environments, streamlining workflows without adding complexity. This next-generation solution represents a major technological advancement over previous versions. Deployed on a new, more compact AR platform, it enhances surgeon comfort, improves overall efficiency, and increases adaptability in the operating room, while ensuring full compatibility with the surgical hood.

Knee+ NexSight provides robotic-level accuracy[1] without the complexity or expense of robotic systems. The instrumentation is less invasive, can reduce blood loss[2], and integrates seamlessly into existing surgical workflows without adding operative time compared to conventional technique[2].

It includes a discreet virtual display directly in the surgeon's field of view, along with voice control, enabling a fully hands-free and intuitive surgical experience. With no disposable components, the system also offers clear economic and environmental benefits.

This solution reflects Pixee Medical's continued commitment to meeting evolving market needs and providing surgeons with the latest AR technologies that combine robotic-level precision with simplicity of use and cost-efficiency. Knee+ NexSight is fully compatible with most primary knee implants and personalized surgical approaches, including kinematic alignment.

Knee+ NexSight received CE mark clearance in February 2026, with initial cases successfully performed in Europe.

"We've always believed that precision in surgery shouldn't come at the cost of usability. With this new AR platform, Knee+ NexSight brings robotic-level accuracy into a system surgeons actually want to use, more compact, fully hands-free, and built to fit the flow of the OR rather than reshape it around itself. FDA clearance now allows us to put that experience in the hands of U.S. surgeons." exclaims Sébastien Henry, CEO of Pixee Medical.

About Pixee Medical

Pixee Medical develops augmented reality solutions for implant placement that offer orthopedic surgeons cutting-edge and clinically proven tools for precise and efficient surgery. Its first generation of products has already been used in over 10,000 procedures in more than 20 countries, demonstrating its positive impact on surgical practices worldwide. To learn more, visit pixee-medical.com

[1] *Lambrechts J, Vansintjan P, Lapierre C, Sinnaeve F, Van Lysebettens W, Van Overschelde. Accuracy of a New Augmented Reality Assisted Technique for Total Knee Arthroplasty: An In Vivo Study. Arthroplasty Today. 2024.*

[2] *Sameer Panchal, Benjamin Barker, Alan James Highcock.*
Improved alignment and reduced peri-operative blood loss with augmented reality-guided total knee arthroplasty: a single-centre comparative study. 2026.