MEDICEPT

Trusted Solutions, Rapid Response

CASE STUDY: POLARIS^{AR} - 510(K) CLEARANCE

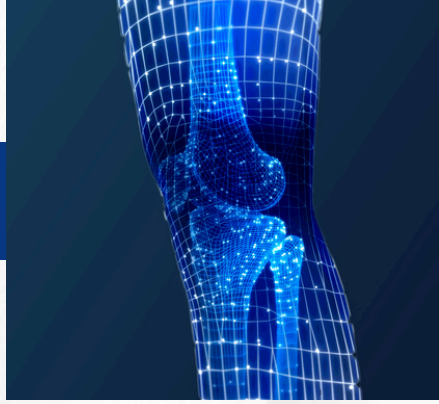

Image from https://thinkpolaris.com/stellar-knee/

BACKGROUND

- POLARIS^{AR} pioneered a new era in surgical technology through the integration of an advanced mixed-reality solution in STELLAR Knee, which delivers real-time, targeted guidance directly onto the surgical field.
- This augmented reality (AR) technology empowers surgeons with robot-like precision during Total Knee Arthroplasty surgeries, without the complexity or costs of traditional robotic systems.
- A 510(k) submission was required to bring their STELLAR Knee AR application to market.

CHALLENGES

- POLARIS^{AR} lacked clarity on the specific regulatory requirements for augmented reality software, causing confusion and delays in the internal development process.
- POLARIS^{AR} experienced foundational issues, delaying the project by about a year due to incorrect software verification and validation processes for the AR-based STELLAR Knee.
- POLARIS^{AR} lacked subject matter expertise to address gaps in their quality system and design controls, impacting their ability to proceed confidently.

SOLUTIONS

- To ensure design controls and submission requirements were met, MEDIcept embedded a regulatory expert from the start to guide the development of the STELLAR Knee AR technology.
- MEDIcept collaborated on drafting the 510(k) and helped the team quickly respond to the FDA's AI letter, allowing the process to stay on track.
- MEDIcept's expertise in software validation and regulatory strategy provided clear guidance and a streamlined process for addressing FDA requirements.

LESSONS LEARNED

- Engaging the right regulatory partner early in the process is essential, particularly for complex AR technologies, to avoid costly delays.
- Outsourcing regulatory expertise allowed POLARIS^{AR} to focus on internal innovation while ensuring compliance with FDA requirements.
- Responding quickly and efficiently to regulatory feedback, as with the AI letter, can drastically reduce time to market.

RESULTS

- FDA received the 510(k) submission and cleared it within 2.5 months.
- MEDIcept's involvement ensured no additional software questions from the FDA, a significant outcome for an augmented reality product.
- The POLARIS^{AR} team became more self-reliant, gaining skills in software risk analysis and compliance that positioned them for future success.

CLIENT TESTIMONIAL

"MEDIcept was instrumental in guiding us through the complex regulatory landscape for our augmented reality surgical technology. Their expertise ensured our 510(k) submission was seamless, and their proactive approach helped us secure FDA clearance faster than we could have imagined. For every small or medium sized company, your search process is only complete once you look at MEDIcept. They empowered our team with the knowledge and skills needed to succeed, setting us up for long-term success."

-Paul Mikus, CEO, POLARIS^{AR}

WHY MEDICEPT?

- Proven expertise in regulatory compliance.
- Embedded, hands on support and training.
- Tailored solutions for our needs.

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