MEDICEPT

Trusted Solutions, Rapid Response

CASE STUDY: SIRA MEDICAL - 510(K) CLEARANCE

Image from https://siramedical.com/

BACKGROUND

- Sira Medical is an early stage medical software company engaged in developing augmented reality software for preoperative planning, patient education, and training.
- A 510(k) submission was required for their augmented reality (AR) preoperative surgical planning application.

CHALLENGES

- Start-up with limited FDA and submission experience.
- Relatively early in FDA's AR thought process.
- Clearance plays a critical role in future funding for the company.

LESSONS LEARNED

- Significant value working with an experienced regulatory consulting company.
- Sira gained a better sense of filing requirements, timing, and cost.

RESULTS

- Received 510(k) clearance.
- No software related questions in FDA's AI request.

SOLUTIONS

- MEDIcept prepared the 510(k), including documentation developed by their Quality Engineering (QE) team in collaboration with Sira.
- MEDIcept provided cybersecurity expertise and risk analysis to address go to market requirements.
- MEDIcept sourced usability testing vendors.

WHY MEDICEPT?

- Stellar references
- Cost-benefit
- Software experience
- Startup experience

CLIENT TESTIMONIAL

"MEDIcept was instrumental in guiding us through the complex FDA clearance process for our novel software product. Their regulatory team was essential, especially with the evolving FDA requirements and the usability process. MEDIcept's risk analysis and cybersecurity consultants provided expertise, ensuring seamless collaboration with our team."

- Rick Beberman, Chief Executive Officer

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