sagentia
innovation

Development of the TMINI™ Miniature Robotic System

THINK Surgical

Development partner of the TMINI™ Miniature Robotic handpiece from THINK Surgical's initial concept to transfer to manufacture.

Expertise and domain knowledge

- Medical product development to ISO13485
- Program planning and management
- Multidisciplinary detailed design
- Systems engineering
- Design for manufacture
- CMO selection and management
- Risk management to ISO14971
- Applicable IEC performance standards for medical devices
- Human factors engineering to IEC62366
- Software development to IEC62304

Our client asked:

Our client, THINK Surgical, selected Sagentia Innovation as their primary development partner of the TMINI™ Miniature Robotic System from THINK Surgical's initial concept through to transfer to manufacture. The TMINI system includes a wireless robotic handpiece that assists Orthopaedic surgeons in performing Total Knee Replacement (TKR). The TMINI robotic handpiece automatically compensates for surgeon hand movement to locate bone pins along precisely defined planes. Cutting guides are connected to the bone pins for accurate bone resection and implant positioning.

Results: deliverables and outcomes

The TMINI robotic system gained 510(k) clearance from the FDA in April 2023.

TMINI system is an exciting step forward in robotics, offering a small footprint, open implant platform and intuitive workflow.

"Sagentia Innovation brought a highly capable and well-integrated team to the table, along with a very sensible iterative development process. This technical expertise complemented that which we hold in-house, and they worked closely with us to develop a differentiated system and enable us to bring the TMINI system to market."

Joel Zuhars, VP of Research and Development at THINK Surgical

The project story:

The program brought together THINK Surgical's extensive domain knowledge in TKR; understanding of 3D optical tracking (provided by an existing partner); and Sagentia Innovation's comprehensive knowledge in medical product development, program management, and expertise in multidisciplinary engineering design.

We applied our depth and breadth of technical program management and engineering skills across the following

- Turnkey subsystem development (TMINI robotic handpiece, battery charger) encompassing electrical, mechanical, and software design, from concept through to verification, pilot builds and transfer to manufacture
- Responsibility for overall program management, system architecture, integration approach, and issue resolution
- Design controls, risk management and DHF management from overall system level to subsystem level
- Responsibility for overall human factor engineering activities and associated documentation to IEC62366
- Development of assembly and calibration fixtures (with associated software), and end-of-line manufacturing test jigs
- CMO selection process and support for procurement, pilot build and early supply chain issue resolution

Contact us

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