

ALKU Case Study Medical Device



Project Overview

EU MDR Technical File Remediation Project

Project Duration: August 2020–Present

Multinational Medical Technologies Corporation

Products include implants used in joint replacement and trauma surgeries, surgical equipment and surgical navigation systems, endoscopic and communications systems, patient handling and emergency medical equipment, neurosurgical, neurovascular, and spinal devices, as well as other medical device products used in a variety of medical specialties.

ALKU Provided

ALKU is the exclusive supplier for contractors on this project. Our consultants are responsible for EU MDR Tech File Remediation and helping our client become compliant with the new European Medical Device Regulations.

ALKU proactively established relationships with Quality, Regulatory, R&D Managers, and decision makers within the company’s elective surgery and orthopedic divisions starting in August 2020. The division was in the planning phase for a large-scale EU MDD–EU MDR transition project and was assessing the need for contractors to support the project workload. Initially, ALKU provided Project Managers to oversee and implement strategy plans for EU MDR Compliance. Throughout the following 14 months, ALKU has provided Design Quality Engineers, Post Market Surveillance Specialists, Biocompatibility SMES, Materials Compliance Engineers, Packaging/Labeling Consultants, and Regulatory/Clinical Affairs resources and more. Throughout the hiring process, ALKU followed up with key stakeholders including Vice Presidents’ and Directors to track the project milestones and consultant production. This follow-up process allowed ALKU to better understand timelines for additional project needs and qualifications for those resources. ALKU became the exclusive supplier for the project and was able to provide a total of 105 additional contractors and counting. This project continues to evolve based on new regulations. ALKU continues to adapt to those changes and provide resources as needed.

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Consultants Placed

