MEDPACE

CASE STUDY

PRE-MARKET CASE STUDY: MEDPACE HELPS ACCELERATE SUBMISSION AND APPROVAL FOR A NON-IMPLANTABLE CARDIAC DEVICE

BACKGROUND

This medical device company seeking FDA approval for a non-implantable cardiac device partnered with Medpace Medical Device for this full-service study that spanned protocol design strategy through preparation and submission of the final 510(k) report.

CHALLENGES

The device itself posed a unique challenge because it was a novel device that would only be available in a limited number of hospitals and few physicians had ever worked with it. To identify, treat and follow up with subjects, multiple subspecialties within cardiology had to be involved in the study—including interventional cardiologists and electrophysiologists—creating scheduling difficulties and more challenging communication paths among the cardiologists and with the study team.

SOLUTIONS

The study was conducted in the United States and United Kingdom, at 13 sites, involving 206 subjects. Medpace Medical Device ensured the study coordinators had all of the tools they needed to navigate scheduling and communication challenges. The physicians were trained by sponsor staff with device simulators and the MMD operations team worked closely with the sponsor to address any additional training needs.

RESULT:

The 510(k) was submitted at an accelerated 48 days after last patient out, significantly outpacing the typical 90-120 days for submission.

The study was two years in duration from initial discussions to final submission, and the 510(k) was submitted at an accelerated 48 days after last patient out, significantly outpacing the typical 90-120 days for submission.

The initial clinical and regulatory strategy was developed to ensure the data could be used for multiple country submissions and the data from this study was used to obtain CE Mark and Health Canada approval.