REGULATORY COMPLIANCE ASSOCIATES® INC

Wellness for Business®

Clearing a Hurdle for CE Mark: The Clinical Evaluation

Client

Breast Biopsy Device Manufacturer.

Industry

Medical Device

Business Challenge

To build a clinical evaluation process to provide relevant information and develop abstracts

Background

Devicor, the leading breast biopsy device manufacturer, wanted CE markings to expand distribution with new products and provide continuity with legacy products obtained through a divestiture. The Medical Device Directive requires a clinical evaluation to verify medical device clinical safety and performance.

Solution

Devicor engaged RCA to build a clinical evaluation process. RCA identified clinical data by conducting literature searches based on key words and phrases, filtered through studies and data for relevant information and developed abstracts for incorporation with Devicor's final submission.

Results

Besides crafting the plan, RCA was instrumental in data collection and analysis of clinical data, reviewing thousands of papers. This expertise helped Devicor complete the submission, leading to the CE Markings and enabling continuity of existing products and expanded distribution of new product. Based on this successful experience, Devicor will gladly look to RCA for future needs in clinical evaluations.

"RCA'S Expertise helped Devicor complete the submissions, leading to the CR markings and enabling continuity of existing products and expanded distribution of new product"

Bruce Marchioni

Senior Vice President of Quality & Regulatory Affairs

Devicor Medical