MCRA Assists SANUWAVE with Successful De Novo Decision for only the 3rd Wound Care De Novo Approved between 2010-2018

Client Need

SANUWAVE is a wound care company with a wound healing system, dermaPACE, that delivers focused, extracorporeal shockwaves to promote wound healing. The dermaPACE system is intended to treat challenging diabetic foot ulcers. SANUWAVE withdrew a PMA submitted previously using data from the first DFU clinical study and recognized the need to enlist MCRA's expertise. At that point, SANUWAVE tasked MCRA with reviewing the clinical study design and results and developing a regulatory strategy to obtain approval.

"We chose MCRA for their extensive regulatory experience and interaction with FDA over the past decade. They took clinical data from, essentially, a Not-Approvable PMA, and worked wonders in obtaining a De Novo decision with basically the same clinical data. Their depth of knowledge and experience in regulatory and clinical science made them an excellent partner for working hand-in-hand with our team and the FDA."
Kevin A. Richardson II, SANUWAVE's Chairman of the Board and CEO

Contact us:
info@mcra.com
202.552.5800

MCRA Approach

MCRA pulled a team of clinical and regulatory experts to review the two studies and assess ways to combine these data into compelling clinical evidence demonstrating safety and effectiveness. MCRA developed a creative strategy to move away from the previously submitted PMA and submit a De Novo application. We worked with our stats partners to develop a rigorous plan for combining the data from the two previously conducted clinical studies and develop a post-hoc evaluation, which successfully demonstrated superiority to the control cohort. This was only the third De Novo granted in the wound care space at the time of the approval in 2018.

MCRA THERAPY: Wound Care

MCRA SERVICES: US Regulatory

Outcome

MCRA was able to turn a rejected PMA and two clinical studies that failed to meet their primary effectiveness endpoints into an approved De Novo product without the need to collect additional clinical data. This successful outcome resulted in clinicians having access to an additional treatment option for debilitating and difficult-to-treat diabetic foot ulcers.