Pain Care Labs Achieves ISO 13485:2016 Certification for Medical Device Manufacturing Quality

Significant milestone opens international access for VibraCool® and Buzzy® device licensing and distribution.

ATLANTA, GEORGIA, USA, July 13, 2021 /EINPresswire.com/ -- Pain Care Labs, a commercial-stage medical device company with a first-in-class mechanoreceptor targeted pain canceling platform, announced today the company received ISO 13485:2016 certification for Medical Device and Quality Management Systems. This certification is a requirement for regulatory purposes and is an international standard that outlines the requirements for a quality management system specific to the medical device industry.

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> *Amy Baxter, MD, Pain Care Labs CEO and Chief Medical Officer*

"As we've transitioned from a tech start-up to neuromodulation platform medtech company, recognition for the quality systems we have in place is important. ISO 13485:2016 is the industry standard our licensing partners recognize, facilitating pharma and hospital-based adoption of our pain relief devices," notes CEO Amy Baxter. "Our VibraCool® line reduces pain after surgery or injury and treats pain from muscle restriction. Our Buzzy® products are used to improve adherence to biologics, vaccines, and lab work. Quality and science-based efficacy have been our core values since our founding; this certification is further evidence of our commitment to safety, product performance, and effectiveness."

ISO 13485:2016 is an internationally recognized quality standard to ensure the consistent design, development, production, installation, and sale of medical devices that are safe for their intended purposes. To be certified, organizations must demonstrate an ability to provide medical devices and related services that consistently meet customer and regulatory requirements.

Pain Care Labs manufactures standard-of-care, FDA registered 510(k) cleared, medical devices. "Because of the sophistication of the mechanical stimulation frequencies used in the devices, and the significant impact on pain and medical procedures, some countries consider our devices to be Class II," notes Director of Global Business Development, Jennifer Tipping. "Our R&D has been largely funded by the NIH, so complying with a world-class quality management system has been in place from the beginning. We are delighted to have official recognition to support our growth worldwide."

About Pain Care Labs

Pain Care Labs (a d/b/a of MMJ Labs, LLC) is the industry leader in non-invasive pain relief solutions. Buzzy® has been used to block pain for over 37 million needle procedures. VibraCool® is an FDA-registered 510(k) cleared device to treat myofascial pain caused by trigger points, restricted motion, and muscle tension. Established in 2006 by emergency physician and pain researcher Amy Baxter M.D., the Company is dedicated to effective, reusable, and affordable solutions for pain. The Company's award-winning solutions are based on patented M-Stim™ and Oscillice®, a mechanical stimulation/thermal neuromodulation platform. Pain Care Labs was named "Industry Leader for Localized Pain Relief" by Frost & Sullivan, a leading market research firm. For more information, including a list of published studies, please visit PainCareLabs.com.

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