

VANCOUVER, CANADA / July 31, 2015 - Biolux Research, designer and developer of Light Accelerated Orthodontics™ technology and products, is excited to announce the receipt of 510(k) marketing clearance for OrthoPulse™ from the US Food and Drug Administration on July 24, 2015.

OrthoPulse™ is a class II prescription medical device as regulated by the FDA, with 510(k) number K143120, and is intended for use during orthodontic treatment in conjunction with aligners or brackets and wires. OrthoPulse™ has already received regulatory approvals in the European Union, Canada, Australia, New Zealand, and other countries.

OrthoPulse™ is a revolutionary new product that utilizes low level light therapy, or photobiomodulation, to stimulate the periodontium and alveolar bone surrounding the roots of the teeth which leads to accelerated tooth movement and reduced treatment time. The device can be used with either braces or clear aligners, thus allowing the doctors and patients to retain choice of preferred mechanics. OrthoPulse™ is a one-size-fits-all soft silicone mouth-guard that patients can use as an easy self-treatment for a short 10 minutes per day, at home or anywhere. OrthoPulse™ has accompanying native apps for iOS and Android platforms that the doctor and/or patient can use to track usage compliance.

“We are thrilled to announce that OrthoPulse™ has received FDA clearance and that we can begin to market the product in the United States,” states Kevin Strange, President and CEO at Biolux Research. “We have made progress with initial market evaluations in Europe and other markets, as well as valuable clinical studies and investigations within the US. We very much look forward to expanding our efforts in key orthodontic markets. The impressive clinical results and experience from our key evaluators and existing customers has been very encouraging; with significant acceleration of orthodontic treatment, we envision that OrthoPulse™ will be a game changer in the world of orthodontics. Patients and doctors want faster treatment and OrthoPulse™ can help them achieve their goals.”

Please visit www.orthopulse.com to learn more about OrthoPulse™, including its technology and clinical dossier, and to place an order.

About Biolux Research

Biolux Research is a world leader in the development of innovative Light Accelerated Orthodontics™ technology and products for use in orthodontics, implantology, and other dentistry markets. Biolux Research focuses on product development and clinical research, and its proprietary, patent-pending technologies have been developed to enhance clinical outcomes and dramatically reduce treatment timelines in orthodontics and dentistry in a safe, effective and non-invasive approach. www.orthopulse.com www.bioluxresearch.com

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