AcceleDentâ„¢ System, Used for Accelerated Orthodontic Tooth Movement, Receives United States FDA Clearance

HOUSTON, Nov. 22, 2011 /PRNewswire/ -- OrthoAccel® Technologies, Inc. [1], developer of the AcceleDent™ System [2], an appliance designed to accelerate orthodontic treatment, announced that it has received FDA clearance and is preparing to launch the product throughout the United States. AcceleDent™ [2] is a simple, removable and non-invasive appliance that a patient with braces wears in the mouth for 20 minutes per day to accelerate orthodontic tooth movement [3]. A randomized, controlled clinical trial [4] conducted at the University of Texas Health Science Center at San Antonio, under the guidance of Dr. Dubravko Pavlin [5], Professor of Orthodontics, demonstrated, with statistical significance, that tooth movement could be accelerated by 106% during the initial alignment phase and 38% to 50% during closure of extraction space. There was no evidence of damage (resorption) of tooth roots or any other adverse events caused by the appliance, thus demonstrating an excellent safety profile. Dr. Pavlin [5] commented, "The evidence for faster tooth movement with the use of AcceleDent™ [2] is welcomed by both orthodontists and patients since it may result in shorter orthodontic treatment time. With an increase in rate of tooth movement observed in our study the orthodontic treatment time could be shortened by at least 5 months during the first two stages of orthodontic treatment. This, together with excellent tolerance, lack of discomfort and ease of use reported by our patients, indicates that AcceleDent™ [2] will likely become an extremely useful tool and valuable adjunct appliance in orthodontic clinical practice."

Michael Kaufman, Vice President of Business Development & Marketing at OrthoAccel® [1], remarked, "We have now completed two clinical trials in the U.S.A. with the AcceleDent™ System [2], and the results have consistently exceeded our expectations. With continuously increasing demand for evidence-based treatments in medicine and dentistry, we are extremely pleased to introduce the first in a series of innovative orthodontic appliances that has the ability to markedly accelerate orthodontic treatment based on sound clinical evidence." The first clinical trial on the AcceleDent™ System [2] was completed under the guidance of Dr. Jeryl English [6] and Dr. Chung Kau [7] at the University of Texas Health Science Center Dental Branch, Houston and has since been published [8].

OrthoAccel® [1] has been selling the AcceleDent™ System [2] outside the U.S.A. since October 2009 where hundreds of orthodontic cases have been treated with AcceleDent™ [2]. As reported by orthodontists, the average orthodontic treatment time has been significantly shortened. Dr. Stewart Hawthorn, a private practice orthodontist in Winchester, UK was among the first in the world to include the AcceleDent™ System [2] into his orthodontic treatment plan. He recently shared, "I am really surprised at how well AcceleDent™ [2] works. It is certainly a useful adjunct to my orthodontic techniques. For those patients who are keen to reduce

their treatment time I would definitely recommend it!" Indicative of the commitment to advance the understanding and efficacy of this appliance through scientific clinical evidence, OrthoAccel® [1] has initiated clinical studies with the AcceleDent™ System [2] in other countries.

The science behind the AcceleDent™ System [2] is the result of years of research by many scientists including Dr. Jeremy Mao [9], Professor of Orthodontics and Zegarelli Endowed Chair at Columbia University College of Dental Medicine in New York. Dr. Mao's [9] pioneering work in the early 2000's, which was initially conducted while he was on faculty at the University of Illinois, Chicago, was paramount in establishing the therapeutic effect of pulsatile forces in accelerating bone modeling and remodeling in the orofacial region. Dr. Mao remarked, "FDA clearance of AcceleDent™ [2] is the culmination of sound scientific principles and proof of concept studies translated into a product that benefits society. Two independent U.S.A. clinical trials and hundreds of cases, in Europe and Australia, with children and adults treated with braces and AcceleDent™ [2], demonstrate accelerated tooth movement."

Dr. Lawrence Levens [10], a private practice orthodontist in St Louis, MO has been anxiously awaiting the arrival of the AcceleDent™ [2] appliance and recently stated his belief that the technology will revolutionize orthodontic treatment for patients. According to Dr. Levens [10], "Orthodontic manufacturers have tweaked brackets and wires for years in the hope of gaining some small advances in shortening the total treatment time patients must wear braces. That area of advancement has been tapped completely. AcceleDent™ [2] has adapted existing technology from orthopedics that has been proven to be safe and effective in causing bones to heal more quickly and applied it to orthodontics. I can deliver the same great care to my patients but much more quickly. Who wouldn't want that?"

About OrthoAccel® Technologies, Inc. [1]
Based in Houston, Texas, OrthoAccel® Technologies, Inc. [1] is a privately owned medical device company currently engaged in the development, manufacturing, and marketing of products to enhance dental care and orthodontic treatment.

About the AcceleDent™ System [2]
AcceleDent™ [2] represents the first successful clinical approach to accelerate orthodontic tooth movement by modulating bone biology in a non-invasive and non-pharmacological manner. The appliance has been studied clinically as a complement to conventional fixed orthodontic appliances. It applies gentle pulsating forces to the dentition and accelerates tooth movement by stimulating a biological response of bone. More information can be found at www.acceledent.com [11] and www.acceledent.co.uk [1] or requested via info@orthoaccel.com [12]

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