



OrthoPediatrics Corp. Receives “Breakthrough Device” Designation from FDA for eLLi™ Growing Rod System for Pediatric Patients with Scoliosis

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WARSAW, Ind., May 02, 2024 (GLOBE NEWSWIRE) -- **OrthoPediatrics Corp.** (“OrthoPediatrics”) (NASDAQ: KIDS), a company focused exclusively on advancing the field of pediatric orthopedics, today announced it has received the “Breakthrough Device” Designation from the Food and Drug Administration (“FDA”) for its new eLLi surgical device, an implant designed to address severe pathology associated with Early Onset Scoliosis (EOS), which can be associated with thoracic insufficiency, a potentially life-threatening condition. eLLi aims to provide a non-invasive means of extending the growing rods that provides increased force, enhanced mechanical reliability, and superior distraction precision, while also addressing safety concerns associated with current technology. eLLi will allow surgeons a new alternative to address deformity of the growing spine with an advanced technology that will complement our efforts to build a platform of EOS technologies. We are proud to have an expert design team comprised of surgeons who have dedicated their careers to treating these unique patients.

According to the FDA, the Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The Breakthrough Program is intended to help patients have more timely access to medical devices by expediting their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the Agency’s mission to protect and promote public health.

David Bailey, OrthoPediatrics’ President & CEO, commented, “Receiving the Breakthrough Device designation from the FDA is a great achievement for our team. This innovative product will be a great addition to our suite of products for pediatric patients with Scoliosis and represents our commitment to continuous innovation and advancing healthcare for children all over the world. I’m incredibly proud of my colleagues for all the work they are doing to deliver novel technologies to our surgeon customers and the KIDS they treat!”

About OrthoPediatrics Corp.

Founded in 2006, OrthoPediatrics is an orthopedic company focused exclusively on advancing the field of pediatric orthopedics. As such it has developed the most comprehensive product offering to the pediatric orthopedic market to improve the lives of children with orthopedic conditions. OrthoPediatrics currently markets 71 products that serve three of the largest categories within the pediatric orthopedic market. This product offering spans trauma and deformity, scoliosis, and sports medicine/other procedures. OrthoPediatrics’ global sales organization is focused exclusively on pediatric orthopedics and distributes its products in the United States and over 70 countries outside the United States. For more information, please visit www.orthopediatrics.com.

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Source: OrthoPediatrics Corp.