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OrthoSpin gets FDA regulatory clearance

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Israel based OrthoSpin Ltd., a portfolio company of The Trendlines Group Ltd., has received regulatory clearance from the United States Food and Drug Administration (FDA) for its smart, robotic external fixation system for orthopedic treatments.

Today, the use of external fixation is a common treatment option for orthopedic-related problems: bone lengthening, setting complex fractures, and correcting deformities. The two main challenges associated with these systems are (1) patient compliance and (2) lack of real-time feedback for the physician. External fixation requires the patient to make multiple manual adjustments every day. This requires significant patient training and involvement and can lead to errors. Many times, the patient does not fully or precisely comply with the mechanical adjustments, which results in less than optimal clinical outcomes.

OrthoSpin's external fixation system addresses the two major challenges of today's manual fixation systems. The smart OrthoSpin system automatically makes pre-programmed adjustments, precisely, and continuously, eliminating manual adjustments and patient training. The OrthoSpin external fixation system delivers a better patient experience and it reduces the need for time-consuming follow-ups.

OrthoSpin CEO Oren Cohen remarked, "Receiving FDA clearance is an exciting achievement for us. We were thrilled at the efficient, fast process. Our robotic struts eliminate the need for manual adjustment, improve patient compliance and the process is expected to be less painful. OrthoSpin's system can monitor biomechanical parameters, and in the future will enable the device to automatically send real-time updates to physicians for following patient progress. This allows fine-tuning of the treatment regimen, if necessary, including a personalized treatment plan for each patient."

Todd Dollinger, Chairman and CEO, The Trendlines Group added: "OrthoSpin's achievement makes us very proud. We look forward to continuing to participate in their progress in improving orthopedic treatment and outcomes."