

# FDA Grants PMA for the AccelStim Bone Growth Stimulation Device — Expanding Orthofix’s Portfolio of Market-Leading Bone Healing Therapy Solutions

5/4/2022

LEWISVILLE, Texas--(BUSINESS WIRE)-- **Orthofix Medical Inc.** (NASDAQ:OFIX), a global medical device company with a spine and orthopedics focus, today announced the U.S. Food and Drug Administration (FDA) pre-market approval for the **AccelStim™** bone healing therapy Class III device. The AccelStim device provides a safe and effective nonsurgical treatment for indicated fresh fractures and for fractures that have not healed (nonunions). The device generates a Low-Intensity Pulsed Ultrasound (LIPUS) signal to stimulate the bone’s natural healing process to promote fracture healing. Commercial availability of the AccelStim device is anticipated to occur in the second quarter of this year through a targeted and phased launch plan.

This press release features multimedia. View the full release here:  
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The Orthofix AccelStim™ bone healing therapy device is indicated for fresh fractures and fractures that have not healed. The device generates a Low-Intensity Pulsed Ultrasound (LIPUS) signal to stimulate the bone’s natural healing process to promote fracture healing.

(Photo: Business Wire)

“As the market leader in bone growth stimulation devices, more than a million patients have been treated with our Pulsed Electromagnetic Field

Stimulation (PEMF) systems,” said Orthofix President of Global Spine Kevin Kenny. “With the addition of the AccelStim device, Orthofix is now the first and only company to offer both PEMF and LIPUS bone growth stimulation devices, and one of only two companies in the U.S. with a fresh fracture indication. We believe that expanding access to patients should help grow the existing \$100M market for fresh fracture LIPUS solutions. This investment and approval further demonstrates our leadership in and commitment to the bone growth stimulation market.”

The AccelStim device is worn externally in the region of the fracture, typically for 20 minutes daily. Treatment length may vary and is determined by the prescribing physician on an individual basis according to the fracture healing progress. The device is lightweight, adjustable and portable, and includes a rechargeable battery that allows

freedom of movement during treatment. The AccelStim system includes a treatment calendar to engage patients in their recovery. The LIPUS technology stimulates bone healing at the molecular, cellular and tissue level and has been proven to accelerate fracture-healing recovery by 38 percent for indicated fresh fractures and an overall clinical success rate of 86 percent for nonunion fractures.

Since 1986, Orthofix Bone Growth Therapy has helped promote the natural bone-healing process in patients. The AccelStim device with LIPUS technology complements the Orthofix portfolio of PEMF bone growth stimulation devices which consists of the **CervicalStim™**, **SpinalStim™** and **PhysioStim™** systems. With the addition of the AccelStim device, Orthofix now provides the most treatment indications in the bone growth stimulation market.

## About Orthofix

Orthofix Medical Inc. is a global medical device company with a spine and orthopedics focus. The Company's mission is to deliver innovative, quality-driven solutions while partnering with health care professionals to improve patient mobility. Headquartered in Lewisville, Texas, Orthofix's spine and orthopedics products are distributed in more than 60 countries via the Company's sales representatives and distributors. For more information, please visit [Orthofix.com](http://Orthofix.com).

## Forward-Looking Statements

This communication contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, relating to our business and financial outlook, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "projects," "intends," "predicts," "potential," or "continue" or other comparable terminology. These forward-looking statements are not guarantees of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict, including the risks described in Part I, Item 1A under the heading Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2021 (the "2021 Form 10-K"). In addition to the risks described there, factors that could cause or contribute to such differences may include, but are not limited to: the risk that surgeons may be slow to adopt the AccelStim device; the risk that future patient studies or clinical experience and data may indicate that treatment with the AccelStim device does not improve patient outcomes as much as previously believed, or otherwise call into question the benefits of its use to patients, hospitals and surgeons; the risk that the product may not perform as intended and may therefore not achieve commercial success; the risk that competitors may develop superior products or may have a greater market position enabling more successful commercialization; the risk that insurance payers may decline to reimburse healthcare providers for the use of our products.

This list of risks, uncertainties and other factors is not complete. We discuss some of these matters more fully, as well as certain risk factors that could affect our business, financial condition, results of operations, and prospects, in

reports we file from time-to-time with the SEC, which are available to read at. Any or all forward-looking statements that we make may turn out to be wrong (due to inaccurate assumptions that we make or otherwise), and our actual outcomes and results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any of these forward-looking statements. Further, any forward-looking statement speaks only as of the date hereof, unless it is specifically otherwise stated to be made as of a different date. We undertake no obligation to update, and expressly disclaim any duty to update, our forward-looking statements, whether as a result of circumstances or events that arise after the date hereof, new information, or otherwise.

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Source: Orthofix Medical Inc.