



# ReVivo Medical

## Press Release

### ReVivo Medical Receives Approval from FDA to Proceed with Clinical Trial

February 16, 2021. ReVivo Medical, LLC announced today that it has agreed upon clinical trial parameters with the FDA that defines a pathway to commercial sales for its flagship devices. “Our goal at ReVivo Medical is to invent and bring to market medical devices that will improve patient outcomes and reduce healthcare costs.” says Gary Mittleman, president and CEO “Obtaining FDA market clearance is our next hurdle.”

ReVivo Medical expects to begin recruiting for the 50-patient clinical study in Q2 2021. The trial is scheduled to take place at the Albany Medical Center and the Cleveland Clinic. Study participants will receive ReVivo Medical’s next generation design anterior cervical plate and interbody cages used in anterior cervical discectomy and fusion procedures. Mr. Mittleman explained that the company has sufficient funds to complete the initial stages of the trial and intends to raise additional funds as the trial progresses.

“Anterior cervical plates and interbody cages are used in over 400,000 surgical procedures each year representing a multi-billion-dollar market,” says Dr. Darryl DiRisio, Professor of Neurosurgery and A. John Popp Chair, Spinal Surgery at Albany Medical Center. “The primary measure of success in these operations is the rapid achievement of bone fusion which thereby stabilizes the spine.”

“Our cervical plate and cage implants are designed to improve bone formation and achieve a superior rate and quality of fusion as compared to the commonly used devices of today,” explains Eric Ledet, PhD., Chief Science Officer. “Additionally, the designs of our implants incorporate unique features that are intended to make them easier for the surgeon to use.”

**About ReVivo Medical, LLC.**, head-quartered in Albany, New York, is developing implantable medical devices for use by surgeons on patients with spinal pathology. The founders, Darryl DiRisio, MD. Professor of Neurosurgery and A. John Popp Chair, Spinal Surgery at the Albany Medical Center and biomedical engineers Eric Ledet, PhD. and Glenn Sanders, PhD. teamed up with the aim of developing products that improve patient health, facilitate easier surgery and reduce costs in this ever-competitive healthcare arena.

*None of ReVivo Medical’s devices are currently cleared for use in the United States.*



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**To learn more please visit our website:**

ReVivo Medical, LLC. [www.revivomedical.com](http://www.revivomedical.com)

or You Tube video link:

<https://drive.google.com/file/d/1ci5OmXd7E2XJMJ1cdE7tsZ6QuP4tPquy/view?usp=sharing>

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**Cautionary Statement Regarding Forward Looking Statements**

This press release contains forward-looking statements that are not purely historical regarding ReVivo Medical's or its management's intentions, beliefs, expectations and strategies for the future, including those relating to the development, cost, size, intended use and technical specifications of the medical products, the potential impact on outcomes and costs associated with spinal surgeries, and the potential profits to be made by ReVivo Medical pursuant to the successful commercialization of their product(s) and the size of market and market share of products. Because such statements deal with future events, they are subject to various risks and uncertainties, and actual results could differ materially from ReVivo Medical's current expectations. Factors that could cause actual results to differ materially include risks and uncertainties such as those relating to: the inability to successfully develop new products and obtain regulatory approval; insufficient outcomes in a clinical trial to achieve clearance; a lack of acceptance in the marketplace by physicians and patients; the inability to manufacture products in commercial quantities at an acceptable cost; possible delays in the company's development programs; the inability of patients or hospitals to receive reimbursement from third-party payors; inadequate protection from patents to prohibit competitors from making similar devices; and inadequate financial and other resources.

All forward-looking statements and reasons why results might differ included in this release are made as of the date of this press release, based on information currently available to ReVivo Medical, and ReVivo Medical assumes no obligation to update any such forward-looking statement or reasons why results might differ.