

## **Zynex Receives FDA Clearance of CM-1600 Monitor for Improved Blood and Fluid Management**

ENGLEWOOD, Colo., June 20, 2023 /PRNewswire/ -- [Zynex, Inc.](#) (NASDAQ: [ZYXI](#)), an innovative medical technology company specializing in the manufacture and sale of non-invasive medical devices for pain management, rehabilitation, and patient monitoring, today announced that the FDA (Food and Drug Administration) has granted 510(k) market clearance for the company's CM-1600 blood and fluid volume monitoring device.

"I am pleased to announce FDA clearance for our second-generation blood and fluid volume monitor," said Thomas Sandgaard, Founder and CEO of Zynex. "Our non-invasive and wireless technology is targeted to improve patient outcomes with better fluid management in hospital settings. The device is based on tracking multiple physiological changes relative to blood and fluid changes in the patient. We will continue to collect additional data in clinical trials going forward and I am eager for the monitoring division to eventually add meaningful revenue to Zynex's already profitable pain management division."

Zynex's division for hospital monitoring products has three additional products in the pipeline: a laser-based pulse oximeter, NiCO™; a monitor for early detection of sepsis; and a non-invasive, laser-based monitor of total hemoglobin levels, HemeOx™. The monitoring division is pre-revenue and expects to submit an application to the FDA for its laser-based pulse oximeter in the fourth quarter of this year.

### **About Zynex, Inc.**

Zynex, founded in 1996, develops, manufactures, markets, and sells medical devices used for pain management and rehabilitation as well as non-invasive fluid, sepsis, and laser-based pulse oximetry monitoring systems for use in hospitals. For additional information, please visit: [www.zynex.com](http://www.zynex.com).

### **Safe Harbor Statement**

This release contains forward-looking statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. The Company makes no express or implied representation or warranty as to the completeness of forward-looking statements or, in the case of projections, as to their attainability or the accuracy and completeness of the assumptions from which they are derived. Factors that could cause actual results to materially differ from forward-looking statements include, but are not limited to, the need to obtain CE marking of new products, the acceptance of new products as well as existing products by doctors and hospitals, larger competitors with greater financial resources, the need to keep pace with technological changes, our dependence on the reimbursement for our products from health insurance companies, our dependence on third party manufacturers to produce our products on time and to our specifications, implementation of our sales strategy including a strong direct sales force, the impact of COVID-19 on the global economy and other risks described in our filings with the Securities and Exchange Commission including but not limited to, our Annual Report on Form 10-K for the year ended December 31, 2022 as well as our quarterly reports on Form 10-Q and current reports on Form 8-K.

Any forward-looking statement made by us in this release is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

**Contact:** Zynex, Inc. (800) 495-6670

**Investor Relations Contact:**

Gilmartin Group  
650 Fifth Ave., Suite 2720  
New York, NY 10019  
[ir@zynex.com](mailto:ir@zynex.com)

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