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Aatru Medical, LLC submits NPSIMS™ product to FDA for Class II Clearance and completes Series C funding

Innovative Negative Pressure Wound Therapy Device for Surgical Incisions

CLEVELAND, July 14, 2020 /PRNewswire/ -- Aatru Medical, LLC ("Aatru") is pleased to announce its recent submission to the FDA of a traditional 510(k) premarket notification application for the company's first product, NPSIMS™ - Negative Pressure Surgical Incision Management System. The submission efforts were led by Aatru President and Board Member Edward Armstrong, in conjunction with Coastal Consulting Group, NAMSA, and DuVal & Associates who provided regulatory affairs and quality assurance support.



"The application submission is the culmination of much work across a range of expertise over the past few years, and we look forward to the time when the product can benefit patients with surgical incisions," said Armstrong.

Aatru has strategically targeted the Negative Pressure Wound Therapy (NPWT) for surgical incision market as there are 250MM annual surgeries globally, with approximately 53MM surgeries in the U.S. resulting in 500,000 surgical site infections ("SSIs") and 8,000 U.S. deaths.



SSIs are the most common cause of hospital readmissions accounting for 19.5% of all readmissions, and these readmissions are a substantial cost burden for all hospital systems.

Additionally, Aatru has just completed its Series C Round of financing by its private investors. The funds will be used to support Aatru's robust product development through FDA clearance and other near-term initiatives.

"Our investors have continued to show strong confidence in our efforts since our inception almost 5 years ago," stated Aatru Chairman and CEO Timothy Wojciechowski. "Because of their support, we have been able to systematically move our NPSIMS™ product from concept to reality, creating an innovative and disruptive alternative to traditional NPWT devices for surgical incisions. We have partnered with best-in-class manufacturers to ensure we meet global demands and have built a substantial portfolio of over 40 patents filed globally to protect our innovation."

Aatru is a privately held medical device technology company focused on disrupting the surgical incision market with its NPSIMS™, a simple, disposable, single-use, patented, low-cost NPWT device, uniquely designed to require no electromechanical pump, battery or canister.

The NPSIMS™ product does not have FDA Clearance and is not for sale at this time.

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