

## Leaf Healthcare, Inc. Receives 510(k) Clearance

**Leaf Healthcare receives clearance by FDA 510(k) to market a system that aids in the prevention of pressure ulcers.**

Newark, CA (November 18, 2013) – Leaf Healthcare, Inc., an innovative medical technology company focusing on wireless patient monitoring solutions, announced today that it recently received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its Leaf Patient Monitoring System designed to assist healthcare providers in their efforts to reduce patient’s risk of developing pressure ulcers.

### **About the Leaf Patient Monitoring System**

Addressing the need for improved pressure ulcer prevention and treatment methods, the Leaf Patient Monitor features a *small wearable wireless body sensor* that enables hospitals, long term acute care facilities (LTAC), and nursing homes to wirelessly monitor the real-time position, movement and activity of patients susceptible to pressure ulcers. This innovative system provides alerts when patient movement or activity deviates from individualized turn management protocols set by the healthcare provider.

“We are excited to receive clearance to introduce this proven safe and efficacious technology that provides caregivers with accurate information regarding a patient’s position and movement over time”, said Mark Weckwerth PhD, Chief Executive Officer of Leaf Healthcare. “An assurance that all patients are repositioned per their prescribed turn protocol is an integral component of successful pressure ulcer prevention programs.”

### **About Pressure Ulcer Prevention**

Pressure ulcers, commonly known as bed sores, are a vast and growing problem in the United States and account for over \$10 billion dollars in annual health care spending. Each year, over 1 million patients will suffer from hospital-acquired pressure ulcers (HAPUs), which often result in extended hospital stays, increased pain, discomfort and can even be a cause of death. Pressure ulcers occur most commonly in the elderly, which is the fastest-growing segment of the population. As a result, the number of patients at risk for developing pressure ulcers is expected to increase dramatically in the coming decades. Given the tremendous burden that pressure ulcers place on the healthcare system, there is a substantial need for improved prevention methods.

“To prevent pressure ulcers, the currently accepted standard of care is to turn high-risk patients at least every 2 hours, day and night,” says Barrett Larson, MD, Chief Medical

Officer at Leaf Healthcare. “In many healthcare facilities, such a turning schedule can be hard to maintain due to nursing workload demands, difficulty monitoring patient position, ineffective turn reminders, and interruptive tasks.”

**About Leaf Healthcare, Inc.**

Founded by Daniel Shen and Barrett Larson MD, Leaf Healthcare creates wireless patient monitoring solutions for health care providers seeking more efficient and cost effective ways to improve patient safety and clinical outcomes. Leaf’s initial product, The Leaf Patient Monitoring System, wirelessly monitors a patient’s position and movement and utilizes that data to automate and document the management of prescribed turn protocols for patients at risk for Hospital Acquired Pressure Ulcers (HAPUs). The company is working to broaden existing product features and capabilities, and develop innovative new technologies that enable more efficient and effective patient care.

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