

***SimplyHome* Now Offers FDA Approved Wireless Telehealth Devices**

SimplyHome leads the industry with FDA approved telehealth devices (used to monitor blood pressure, pulse, blood oxygen levels, glucose and weight) that guarantee patient data is securely transmitted to ensure proper treatment.

Asheville, N.C.

SimplyHome is now introducing an FDA approved telehealth product suite in preparation for an FDA rule that will be finalized this October. The rule states that IT companies will be required to register health care hardware and software that transfers, stores, converts or displays health care data.

Some devices that have not been FDA approved, but are being used to transfer patient data, present a potential risk to patients if they do not work as intended. For example, if the wrong reading is transferred to a website for a doctor to view, the doctor could potentially prescribe the wrong medication or dosage to the patient. There are several telehealth options available right now on the market but not all of them are FDA approved.

“The FDA approval represents a level of scrutiny so a customer can be confident that they are using a product of the highest quality possible,” says Jason Ray, *SimplyHome* VP of Business Development.

SimplyHome uses the term “telehealth” when referring to tools they offer used to remotely monitor blood pressure, pulse, blood oxygen levels, glucose and weight. Each reading is taken and then wirelessly transmitted using bluetooth to a base station that collects the data and then sends each reading to a confidential and personalized website. Then, after customizing an individual’s profile, family, medical personnel, and caregivers can receive instant notifications if health parameters are in a range of concern.

The benefits of telehealth technology are:

- Promote preventative care
- Support overall wellness
- Cut down on hospital readmissions

Each device used to test blood pressure, pulse, blood oxygen levels, glucose and weight must be individually approved by the FDA. Not only that, but all of those readings need to be transported to a central device so those readings can be logged to view trending activity, pin-point potential problems and set up alert rules and that device must be FDA approved as well. Some companies have built their own portal or base station to collect this data, but have not gone through the FDA approval process yet.

The United States Food and Drug Administration (FDA) is the federal governmental agency charged with protecting the health and welfare of the American public through the regulation of food, drugs and medical devices. When a product is FDA approved, it means that EVERY aspect or component of the device, including any claim found on the device, has been scientifically proven to be valid, safe and effective. It also includes a thorough FDA inspection of the laboratory and facilities, in addition to intense review of the validity of the computer system's hardware and software. It is against the law for any product or service to claim it is FDA approved when it is not.

When equipment or software is intended for use in the diagnosis or treatment of a disease or other condition, the FDA considers the equipment or software to be a medical device. The FDA also regulates the software used in telehealth systems.

“We feel a responsibility as a company to make sure we are providing solutions that meet FDA requirements so customers can rest assure that their purchases will meet regulatory requirement long before they are being enforced,” says Jason Ray, *SimplyHome* VP of Business Development.

About *SimplyHome*

SimplyHome designs and installs wireless technology products and related care-focused services. The company is committed to promoting affordable and dignified solutions for independent living – specifically to aging and disabled populations nationwide. *SimplyHome* is known for its highly-customizable systems that are tailored to meet each customer’s specific needs.

SimplyHome products and services range from voice-activated environmental controls (as seen on *Extreme Makeover: Home Edition*), Personal Emergency Response Systems, GPS watches, motion sensors, and stove monitors to Virtual Care Management® – *SimplyHome*’s model for client care. *SimplyHome* is a 2012 Edison Award winner for “Best New Product.”

For more information, visit: www.simply-home.com .

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