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# PneumaCare receives FDA 510(k) clearance for Thora-3DI imaging device

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PneumaCare Ltd (Cambridge, UK) announced that it has received 510(k) clearance from the US Food and Drug Administration (FDA) for its Thora-3DI™ imaging device.

Thora-3DI™ is a non-invasive, non-contact device that uses a patented technology known as structured light Plethysmography (SLP) to measure breathing through detection of movement of the chest and abdomen. The technology can be used to accurately measure respiratory status in patients with a wide range of respiratory conditions, including asthma, chronic obstructive pulmonary disease (COPD), pneumonia and lung failure, and to assess patients before and after surgery. The SLP technology uses safe white light to project a grid pattern onto the chest, and record accurate 3D images of chest wall movements over time. The measurements are converted into visual and numerical outputs, which can help clinicians to make faster diagnoses and treatment decisions, and continually monitor patients in real time, without direct patient contact or intervention. The Thora-3DI™ is mobile, and can easily be moved between wards, or dismantled for transport and use in the community or in clinics.

Stringent bench and clinical validations required for the FDA 510(k) clearance have demonstrated that the Thora-3DI™ system can detect movements as small as 0.25 mm, and can accurately measure respiratory rate to within less than one breath per minute when compared with the FDA gold standard reference device. The device is indicated for hospital or clinical use and is intended to be operated by clinicians and medically qualified personnel.

Mark Harwood, PneumaCare's CEO, stated, *"We are delighted to receive FDA approval for our revolutionary product, which brings benefits for doctors and patients alike. Thora-3DI™ is a first-in-class product that will be of wide interest to respiratory physicians worldwide. 510(k) clearance builds on the success of our CE mark authorisation for the product in Europe, achieved in 2012. A number of clinical trials continue to demonstrate major benefits of respiratory assessment using the* Thora-3DI™, and *publication of trial data are in progress. We believe that these results will have significant implications for patient care in a range of clinical areas."*

Dr. Bill Mason, Chairman of PneumaCare *said, "FDA 510(k) clearance for* Thora-3DI™ *is a very exciting moment in our company history, but even more so for respiratory physicians globally, who will now have access to our product for the first time. The Company has met and surpassed the stringent criteria imposed by FDA for clearance to market medical technology, through a process that has taken nearly two years of hard work and intense consultation with the regulatory authority. I am very proud of our team for attaining this major achievement and also extend much gratitude to our shareholders, who have supported the company throughout the development of this innovative approach to an unmet clinical need*."

Source:
PneumaCare Ltd