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InfraScan Launches International Sales of a Handheld Brain Hematoma Detector

Handheld imaging device for early detection of brain bleeding in head trauma patients receives CE Mark authorizing sales in Europe, Asia and Africa

Philadelphia, PA – October 21, 2008 – InfraScan, a medical device firm specializing in brain injury diagnostic products, announced today that it has obtained the CE mark, European marketing clearance, for the Infrascanner handheld brain hematoma detector. The CE Mark certifies that the product (Infrascanner) has met European Union (EU) health, safety and environmental requirements. InfraScan plans to launch international sales this fall.

“Receiving our CE mark represents significant progress toward InfraScan’s strategic goal of providing our potentially life saving technology to patients in some of the world’s top established and emerging markets,” said Baruch Ben Dor, PhD, president and CEO of InfraScan. “Earlier this year, InfraScan passed a British Standards Institute audit and received ISO 13485:2003 quality certification. This facilitated our obtaining the CE Mark for the Infrascanner and allowed us to sign our first distributors in the UK, Spain, Israel, India and Africa.”

The Infrascanner brain hematoma detector is the first hand-held device of its kind designed to assist first responders and emergency room personnel in identifying life threatening brain hematomas, allowing expedient assessment of patients and potentially facilitating crucial treatment. Intracranial hematomas resulting from a traumatic brain injury are life-threatening and patient outcomes can improve significantly if treated within an hour after an injury – known as the “golden hour”. While most hospitals have a Computer Aided Tomography (CAT) scanner, which is viewed as the state-of-the-art technology for diagnosing a brain hematoma, many facilities lack the neurosurgical capabilities to treat the condition. The early identification of a brain hematoma can play a significant role in facilitating transportation of critically injured patients to facilities, which can both verify Infrascanner’s early diagnosis and offer surgical intervention.

The Infrascanner is a small, completely portable device, which can detect the presence and location of a brain hematoma based on differential NIR light absorption of a hematoma and normal brain tissue. InfraScan will present the results of a pivotal (400 patient) multicenter study to the FDA later this year to support its 510k application and a subsequent U.S. launch of the device. A pilot study with an earlier Infrascanner prototype involving more than 300 patients demonstrated high sensitivity for detecting bleeding in the brain and for rapidly detecting the onset of delayed hematomas.

An estimated 1.5 million individuals seek medical treatment for head trauma in the U.S. each year, and a total of 10 million individuals seek head trauma treatment annually worldwide. In addition to the Infrascanner’s first application for detecting brain hematomas, the company will pursue future applications for the product, including the monitoring of stroke victims using the same NIR technology.

About InfraScan – InfraScan, Inc. is a medical device company that focuses on developing, commercializing and distributing hand-held diagnostic devices for head injury and stroke based on near infrared (NIR) technologies. The company has received early-stage funding from the Office of Naval Research, BioAdvance, the Biotechnology Greenhouse of Southeastern Pennsylvania, Ben Franklin Technology Partners of Southeastern Pennsylvania, and from the Philadelphia Industrial Development Corporation. For more information visit www.infrascanner.com.

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