

FDA APPROVES HAND-HELD DEVICE FOR DETECTING INTRACRANIAL HEMATOMAS

The U.S. Food and Drug Administration (FDA) has approved marketing of the first hand-held device intended to aid in the detection of life-threatening bleeding in the skull called intracranial hematomas, using near-infrared spectroscopy. According to the Centers for Disease Control and Prevention, each year about 1.7 million people in the United States experience a traumatic brain injury. The device, called the Infrascanner Model 1000, manufactured by InfraScan Inc. of Philadelphia, can help health care providers identify patients with critical head injuries who need an immediate brain imaging study. The device was able to detect nearly 75% of the hematomas detected by CT scan. When CT scans detected no hematoma, the device detected no hematoma 82 % of the time.

No information was provided on the cost of the device or on whether its target purchasers would include pre-hospital providers.