FDA Permits Marketing of the First Hand-Held Device To Aid in the Detection of Bleeding In The Skull

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SILVER SPRING, Md., Dec. 13, 2011 /PRNewswire-USNewswire/ -- The U.S. Food and Drug Administration today allowed 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.

(Logo: http://photos.prnewswire.com/prnh/20090824/FDALOGO [1])

The device, called the Infrascanner Model 1000, can help health care providers identify patients with critical head injuries who need an immediate brain imaging study.

Intracranial hematomas occur when blood from a ruptured blood vessel collects within the brain or between the skull and the brain. As blood expands within the brain or in the narrow space between the brain and the skull, the brain becomes compressed. This can produce symptoms such as headaches, vomiting, dizziness, lethargy, weakness in the arm or leg on one side of the body, seizures, or unconsciousness. An intracranial hematoma can be life-threatening if it is not treated immediately.

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 Infrascanner, Model 1000, uses a scanner that directs near-infrared light, a wavelength of light that can penetrate tissue and bone, into the skull. Blood from intracranial hematomas absorbs the light differently than other areas of the brain. The scanner detects differences in light absorption (optical density) and transmits the information wirelessly to a display on a hand-held computer.

By comparing the optical density from a series of scans of specific areas on both sides of the skull, a trained health care provider can use the information provided by the device, in conjunction with other clinical information, to determine the likelihood of an intracranial hematoma and the need for further diagnostic proc
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