



Jan Medical Enters into Agreement with US Army for Investigational Device for Concussion Diagnosis

BrainPulse™ device was evaluated by US Army Medical Materiel Agency

MOUNTAIN VIEW, April 10, 2018 — [Jan Medical](#), a medical technology company, announced today that it has conducted its first user feedback session as part of a cooperative research and development agreement with the U.S. Army Medical Materiel Agency. During the tests, which took place on March 9th, the U.S. Army evaluated the [BrainPulse](#) device and provided feedback for future development and revisions. BrainPulse, an investigational device, is used to detect brain disorders as well as injury, such as concussion¹.

“The BrainPulse device by Jan Medical, Inc. was identified as a potential product through market research efforts based on the Federal acquisition regulation part 10. Our goal is to provide clinicians with the capability to non-invasively diagnose mild brain injury in field and pre-hospital settings,” said Brian Dacanay, Product Manager at the U.S. Army Medical Materiel Agency, a subordinate organization of the U.S. Army Medical Research and Materiel Command. “Unlike brick and mortar hospitals where conditions are controlled and ideal, medical devices may not operate in the field environment, especially when exposed to extreme environmental conditions. Making hardware or software modifications as the device is being developed will help assure that medical devices can operate in the field and reduces overall developmental costs. User feedback is essential because it allows developers to incorporate hardware and software modifications early in the process.”

A user assessment of BrainPulse was completed at Fort Bragg, North Carolina, the largest military installation in the world with over 50,000 personnel in active duty. Simulations were performed to replicate how the device would be used in the battlefield by medics and physicians. Due to its small size, portability and battery power source, the device is ideal for transportation and may be considered for use as a triage tool in Battalion Aid Stations and medical treatment facilities.

“Jan Medical is honored to be working side by side with U.S. Army based clinicians to advance our next-gen device,” said [Ken Bruener](#), President of Jan Medical. “BrainPulse will provide diagnostic indicators for urgent brain disorders, including concussion, allowing for rapid diagnosis of head injuries in both military and civilian populations.”

Blood flow to the brain during each heartbeat is not symmetrical due to the distribution of arteries into the head, which cause the brain to oscillate inside the skull. With highly sensitive sensors in the headset, BrainPulse is designed to detect any abnormalities in this oscillation, which may indicate disease or injury. The results are analyzed by complex algorithms and then displayed on a touchscreen tablet for the physician, nurse or trained medical personnel to interpret. The whole process, from set-up to a complete recording, takes between three to five minutes.

BrainPulse has received De Novo clearance from the U.S. Food and Drug Administration (FDA) as a class II device for cranial motion measurement. As part of the agreement, the U.S. Army will also provide regulatory guidance and advice as Jan Medical seeks FDA clearance on their concussion indication for the BrainPulse device.

To learn more about BrainPulse, visit janmedical.com.

About Jan Medical

Jan Medical is a medical device start-up dedicated to providing physicians critical data for accelerating and expanding therapy while improving the diagnostic experience for patients with brain disorders.

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¹ The BrainPulse system is an FDA cleared device for cranial motion measurement currently under research for a variety of neurological conditions. Limited by federal (US) law to investigational use for diagnostic purposes.