FDA Grants Clearance for Longeviti's Off-The-Shelf ClearFit® Cover, Accelerating Capability of Ultrasound Imaging after Complex Brain Surgery

Longeviti Neuro Solutions, developer of the first low-profile intracranial devices that meets the functional and reconstructive needs of brain surgery patients, recently announced that it was granted a 510(k) clearance by the U.S Food and Drug Administration (FDA) for ClearFit® OTS (off-the-shelf).

BALTIMORE (PRWEB) November 18, 2021 -- Longeviti Neuro Solutions, developer of the first low-profile intracranial devices that meets the functional and reconstructive needs of brain surgery patients, recently announced that it was granted a 510(k) clearance by the U.S Food and Drug Administration (FDA) for ClearFit® OTS (off-the-shelf). With the new 510(k) clearance, Longeviti is the first solutions provider to bring an optically clear, polymethyl methacrylate, off-the-shelf cranial product to the market— enabling surgeons to address urgent, immediate functional and reconstructive clinical needs with the latest technological advancements in neurosurgery.

The ClearFit® OTS product line provides implantable prosthetics to correct and restore cranium bone voids, while also enabling the use of ultrasound for post-operative imaging. The ClearFit® OTS is an extension of the company's original ClearFit®.

"There is a real need for a product like the ClearFit® OTS, which allows us to utilize this innovative solution when performing cranial surgery under emergency circumstances," said Justin Singer, MD, Neurosurgeon at Spectrum Health Butterworth Hospital in Grand Rapids, Michigan. "This breakthrough technology is a game changer for surgeons like myself, and will greatly benefit our patients and their ongoing care. The combination of the reconstructive application and post-operative imaging through ultrasound, in a product we can immediately access, is a significant milestone in our ability to perform complex brain surgery."

The ClearFit® OTS products are made of polymethyl-methacrylate (PMMA), a sonolucent, biocompatible material with over 40 years of proven clinical performance. The product line is the first-of-its-kind and allows neurosurgeons to use ultrasound imaging post-operatively, reducing radiation exposure.

Research has shown that current post-neurosurgical imaging modalities carry risks due to radiation exposure, and that approximately 29,000 future cancers could be related to CT scan use in the U.S. per year (1).

"The patient is, and always will be, our focus as we continue to develop new neurological solutions," said Jesse Christopher, CEO of Longeviti. "We're thrilled to bring the ClearFit® OTS to market, as it grants a new pool of patients access to life-enhancing technology. We're looking forward to working with surgeons to bring this innovative solution to more patients around the globe."

About Longeviti
Longeviti is advancing neurosurgery through the development of low-profile intracranial implants that address the functional and reconstructive needs of patients with neurological conditions. Since 2018, the company has brought several FDA-cleared implants to market. Longeviti's focus is to develop innovative solutions for complex brain surgery that return patients to anatomical normalcy. For more information, visit www.longeviti.com and follow Longeviti on Twitter or LinkedIn.

(1) Biological Effects of Ionizing radiation VII Phase II. National Academics Press 2006; Smith-Bindman R. Arch Int Med 2009

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