U.S. FDA 510(k) Clearance for BodyTom® 64 Portable CT Scanner

NeuroLogica Corp., (represented in India by SCHILLER) a subsidiary of Samsung Electronics Co. Ltd., announced that its head-to-toe trauma imaging solution, BodyTom® 64 Point-of-Care Mobile Computed Topography (CT) Scanner has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for commercial use in the United States.

Portable CT machines have increased patient access to imaging services, as well as responsiveness to patients' specific needs. A key point here is the mobile CT's capacity to perform imaging exams on a patient without the need for repositioning and limiting patient movement, making CT scans feasible even for the most unstable and critically ill patients. In fact, when transferring critically ill patients for imaging, the incidence of adverse events can be as high as 71%, with transportation risks that include critical equipment becoming compromised (such as monitoring devices, intubation tubes, intravenous lines), and physical concerns such as hypotension, hypoxia, and increased intracranial pressure. Even if the transport team is well-trained and made up of experienced, senior staff, adverse events still occur about 15% of the time. A portable CT scanner can reduce these adverse events significantly, saving lives.

BodyTom® 64 is a full-body 64-slice CT scanner that is an upgraded version of the BodyTom® Elite CT scanner 32 Slice, providing enhanced functionality with high-resolution imaging capabilities. Based on customer feedback, the company designed BodyTom® 64 to enhance the user experience and improve clinical workflows through revisions to both the software and the data acquisition system (DAS). Such revisions include incorporating Linux as the operating system and having the ability to generate up to 64 cross-sectional CT images of a patient's body, as compared to the 32 images produced by the predicate BodyTom® Elite.

With indications for both paediatric and adult imaging, the BodyTom® 64 is a multi-departmental imaging solution that can be utilized for various needs, including:

1. **Neurosurgery/ Surgery**: When combined with any radiolucent skull fixation device, the BodyTom® 64 can transform an operating room into an intraoperative neuro-imaging suite to enhance neuro-navigation and surgical outcomes, including clinical utility for extracranial procedures.
2. **Trauma/ ER**: The unique combination of internal lead shielding and battery operation of the BodyTom® 64, allows any standard trauma bay to be transformed into an advanced CT imaging suite.
3. **Interventional Radiology**: BodyTom® 64 can help optimize workflows by rescanning each stage of needle guidance as and when required thereby bringing the power of multi-slice CT to the interventional suite.

BodyTom® 64 is designed and manufactured to comply with the FDA Quality System Regulations and ISO 13485:2016 requirements and is in conformance with global regulatory harmonized standards.