GE Healthcare Submits the Final Module of Its Premarket Approval Application (PMA) for GE Breast Tomosynthesis Option

Business Wire

GE Healthcare, a unit of General Electric Company (NYSE:GE), announced that it recently submitted to the U.S. Food and Drug Administration (FDA) the final module of its premarket approval application (PMA[1]) for GE Breast Tomosynthesis, an option of the Senographe Essential system.

In this final PMA module, GE Healthcare has provided the FDA with clinical study results and manufacturing information. The GE Breast Tomosynthesis option has been designed as an add-on option for the Senographe Essential that will acquire multiple projection views to produce 3D Digital Breast Tomosynthesis (DBT) images, intended to be suitable for screening and diagnosis of breast cancer. GE has a large Senographe Essential and Care installed base in clinical use in the USA.

Over 1700, Senographe Essentials are in clinical use in the United States today.

“Across GE Healthcare we continue to innovate our portfolio and offer complete solutions that meet the needs of our global customers, while helping to provide more access to quality healthcare at a lower cost. In particular within the Women’s Health business, we aim to help clinicians expand care to more women globally in order to help reduce breast cancer and since 1965 have continued to make progress in providing solutions for breast cancer detection and diagnosis across the breast care continuum,” said Prahlad Singh, General Manager, Women’s Health, GE Healthcare - Detection & Guidance Solutions (DGS).

First shipments have started in Europe, Middle East, Australia and Latin America with a solid flow of customer sites placing orders.

1 1GE190-004 BIE (Blinded Imaging Evaluation) study – US. A Multicenter Study to Test the Non-Inferiority of Digital Breast Tomosynthesis Compared to FFDM in Detecting Breast Cancer