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Carestream Health Receives Approval Letter From FDA For CR Mammography System

ROCHESTER, N.Y., Nov. 4 — Carestream Health has received an approval letter from the U.S. Food and Drug Administration (FDA) for its high-resolution computed radiography (CR) system for mammography. Once the FDA approves the final product labeling, Carestream Health can immediately begin commercial distribution of this innovative CR system for mammography in the U.S.

The company's CARESTREAM DIRECTVIEW CR Mammography Feature enables mammography images to be captured digitally while utilizing a healthcare provider's existing mammography x-ray unit and workflow processes. It is intended for use in the same clinical applications as traditional screen-film based mammography systems.

"Annual mammograms for women are important for good health and our CR mammography system will provide healthcare organizations with yet another option for providing high-quality screening for breast cancer," said Dina Vazzana, General Manager, Women's Healthcare, Carestream Health. "This high-performance, cost-effective system will enable medical facilities to benefit from advanced digital medical imaging technology in a way that complements their patient-focused operations."

This optional mammography feature is available when purchasing a new CARESTREAM DIRECTVIEW Elite, Classic or CR 975 System, or as a retrofit to installed Elite, Classic or CR 850/950/975 systems.

With this feature, Carestream Health's CR systems can be used for both general radiography and mammography exams. In addition, the optional CARESTREAM DIRECTVIEW

CR Mammography Total Quality Tool is available to streamline objective mammography image testing and QC measurements.

Carestream Health's CR mammography feature has been selling successfully in Europe, Greater Asia, Japan and Latin America since 2005. The company has installed thousands of systems with its mammography capability in healthcare facilities such as clinics, breast imaging centers and hospitals.

In addition, the company's CR mammography feature has previously received regulatory approval from Health Canada and Carestream Health has been successfully selling this system in Canada since 2007.

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About Carestream Health

Carestream Health is a worldwide provider of dental and medical imaging systems and healthcare IT solutions; molecular imaging systems for the life science research and drug discovery/development market segments; and x-ray film and digital x-ray products for the non-destructive testing market. For more information about the company's broad portfolio of products, solutions and services, please contact your Carestream Health representative or visit www.carestreamhealth.com.

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