Lexmark Healthcare Receives FDA 510(k) Class II Clearance for NilRead Enterprise Viewer

Clearance includes the entire NilRead product family and covers a wide variety of medical imaging studies, including mammography and digital breast tomosynthesis (DBT)

LENEXA, Kan.

News Facts

- [Lexmark](#) announced today that it has received 510(k) Class II clearance from the U.S. Food and Drug Administration (FDA) for Lexmark NilRead, a web-based, zero-footprint enterprise diagnostic viewer. The NilRead viewer is available in multiple configurations – core, clinical and interpretation – covering different workflows ranging from the distribution of imaging studies and reports within the enterprise to full primary interpretation workflows in decoupled enterprise image management implementations.

- Lexmark acquired Toronto-based Claron Technology, Inc., including its NilRead line of medical image viewing, distribution, sharing and collaboration products, in January 2015. NilRead is part of Lexmark's Healthcare Content Management (HCM) suite of solutions designed to enhance a clinician's ability to make informed decisions by providing a comprehensive view of all relevant patient information in context of the patient. Lexmark HCM provides greater interoperability of patient content as healthcare delivery organizations move to an enterprise approach to managing medical images and other healthcare content that typically exists outside the electronic medical record (EMR) and other core applications.

- The 510(k) Class II clearance by the FDA means healthcare organizations in the U.S. are now able to use Lexmark NilRead to perform diagnostic review and interpretation of a wide variety of medical imaging studies, including mammography and digital breast tomosynthesis (DBT) studies. The zero-footprint design of NilRead enables these large files to be delivered throughout a healthcare enterprise to local clinician workstations without download wait times. This is significant in a mammography screening environment where the daily volume of imaging studies reviewed is high.

- Each Lexmark NilRead configuration provides physicians with secure, interactive processing, viewing, and sharing of 2D, MPR, 3D, and Fusion radiology exams. It provides interactive image processing and visualization tools and rule-based exam viewing to support physician preference and multi-monitor display configuration. NilRead can be easily integrated with any DICOM or HL7 network, connected with a vendor neutral archive (VNA) and invoked from a radiology information system (RIS) or workflow/reporting solution. NilRead can also query-retrieve remote DICOM and Web DICOM nodes, XDS repositories and other medical archives.

- As healthcare organizations move to an enterprise approach for managing medical images and other healthcare content, Lexmark NilRead functions as the enterprise viewing solution that gives clinicians universal access to all patient imaging through the EMR, electronic health record (EHR) or health information exchange (HIE). NilRead also supports dedicated interpretation workflows for radiology and other specific departments. With NilRead, referring physicians and diagnosticians are able to work together more effectively to treat patients without the constraints of service line silos. Clinicians are able to quickly and efficiently access and interact with images and reports for all patient images in a single view across the enterprise.

- Along with enterprise viewing, Lexmark's full array of healthcare content management solutions includes VNA, document management, enterprise image connectivity, open image exchange and managed print services. These solutions are capable of being implemented together or separately to integrate with a healthcare organization's existing applications.

- Lexmark is positioned as a "leader" in Gartner's most recent Magic Quadrants for enterprise content management, enterprise search and managed print services.

- Lexmark's enterprise image connectivity solutions are used by half of all U.S. hospitals.
- One hundred percent of U.S.-based HIMSS Stage 7 healthcare systems use Lexmark products and

solutions.

Supporting Quotes

"Lexmark is playing a large role in the movement today within healthcare to centralize the management of medical images and other healthcare content for improved access and consumption by physicians in treating patients," said Claudio Gatti, founder of Claron Technology and now chief technology officer, visualization, Lexmark Enterprise Software. "The new 510(k) Class II clearance by the FDA, the first for a zero-footprint solution to include support for mammography and DBT, enables Lexmark to provide a unified experience all the way from referral viewing to full primary interpretation. With this new clearance, NilRead now provides even greater clinical value, IT efficiency and cost savings to our healthcare provider clients as a truly universal viewer for a wide variety of uses across the enterprise."

"Healthcare organizations are rapidly moving away from managing patient medical images and other content at a departmental level toward an enterprise approach that provides comprehensive, cost-effective access and sharing of this content across and beyond enterprise boundaries," said Amie Teske, director of healthcare industry solutions, Lexmark. "NilRead provides the enterprise viewing component of a full healthcare content management strategy that allows our customers to gain control of patient content and improve the productivity of clinical staff while providing a more patient-centric approach to care delivery."

Supporting Resources

- [Claudio Gatti video](#)

- [InContext healthcare news and trends](#)

- [Lexmark Healthcare on LinkedIn](#)

About Lexmark

Lexmark (NYSE: LXK) creates enterprise software, hardware and services that remove the inefficiencies of information silos and disconnected processes, connecting people to the information they need at the moment they need it. Open the possibilities at www.Lexmark.com.

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