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Approvals

FDA Clears First Diagnostic Radiology Software Application for Apple iPhone, iPad

A new mobile radiology application cleared by the Food and Drug Administration Feb. 4 will allow physicians to view medical images on Apple devices such as an iPhone and iPad.

FDA said the application, Mobile MIM, is the first the agency has cleared for viewing images and making medical diagnoses based on computed tomography (CT), magnetic resonance imaging (MRI), and nuclear medicine technology, such as positron emission tomography (PET).

The application is not intended to replace full workstations and is approved for use only when there is no access to a workstation, FDA said.

According to FDA, radiology images taken in the hospital or physician's office are compressed for secure network transfer, then sent to the appropriate portable wireless device using the Mobile MIM software.

Mobile MIM, manufactured by Cleveland-based MIM Software Inc., allows the physician to measure distance on the image and image intensity values and display measurement lines, annotations, and regions of interest. The company said on its website that the product received a 510(k) clearance (premarket notification) from FDA, but the agency did not explicitly mention 510(k) in its statement.

''This important mobile technology provides physicians with the ability to immediately view images and make diagnoses without having to be back at the workstation or wait for film,'' William Maisel, chief scientist and deputy director for science in the FDA's Center for Devices and Radiological Health, said in an agency statement.

Because the displays on mobile devices can experience variations in brightness levels even between devices of the same model, the Mobile MIM application includes an interactive contrast test in which a small part of the screen is a slightly different shade than the rest of the screen. If the physician can identify and tap this portion of the screen, FDA said, then the lighting conditions are not interfering with the physician's ability to discern subtle differences in contrast.

Significant Advance. Bradley Merrill Thompson, an attorney at Epstein Becker & Green in Washington, told BNA that Mobile MIM is ''exactly where the mobile health industry is trying to head.''

''Being able to make broader use of available mobile technologies to improve the efficiency of health care, while at the same time improving quality by making the health care system more responsive to patient needs for timely diagnosis, represents a significant breakthrough,'' Thompson said. Thompson is one of the founders of the mHealth Regulatory Coalition, which is composed of information technology developers and vendors and IT industry groups.

Peter Connolly, an attorney at Holland & Knight in Washington, said that with the agency's clearance of the application, ''medical diagnoses enter the age of wireless mobility. No longer will doctors be required to be at their workstations in order to diagnose medical conditions through the viewing of CT or MRI or other medical images.''

The benefits to patients and doctors from being able to make preliminary diagnoses before viewing the full image back at the office will be immense, Connolly said.

Michael Gaba, an attorney at Holland & Knight, told BNA, ''This breakthrough, giving physicians greater flexibility to provide diagnostic services wherever they are, may very well force a rethinking of reimbursement rules that require physicians to be in close proximity to their patients when rendering care. Another example of innovation outpacing the law, as it should be.''

Keith Barritt, an attorney at Fish & Richardson in Washington, said that the product's apparent clearance through the 510(k) process ''would be a victory for the entire wireless medical device industry.''

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The 510(k) process is the way the majority of medical devices reaches the market, and requires devices to be ''substantially equivalent'' to a legally marketed predicate. The agency's overall use of 510(k) is under internal review (5 MELR 47, 1/26/11), and the agency also is awaiting a report this year from the Institute of Medicine on the topic.

Barritt said the MIM product ''is apparently the same, or closely similar, medical software that was rejected by the FDA about one year ago due to lack of an appropriate predicate device.''

Barritt noted that the reported indications for use of the newly cleared product are limiting, because FDA makes it clear the software is for use only when there is no access to a workstation, and that the software is not intended to replace full workstations.

''While clearly a big step for MIM Software and the industry in general, this limitation reflects the FDA's cautious approach with the use of mobile health technology,'' Barritt said.

By Nathaniel Weixel

More information about the product is at http://www.mimsoftware.com/.

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