

Momentum Continues for Digital Pathology

► **FDA clears reading of Aperio's digital progesterone receptor slides on computer monitor**

►► **CEO SUMMARY:** *Last month, digital imaging in pathology gained additional momentum with the latest FDA clearance. Aperio Technologies, Inc., now has FDA clearance to market its slide scanning system for reading digital progesterone receptor (PR) slides on a computer monitor. Aperio plans to file an application next year with the FDA for clearance to use its digital pathology imaging system for the reading of digital H&E breast tissue slides on a computer monitor.*

USE OF DIGITAL SLIDE IMAGES for primary diagnosis in anatomic pathology took another step closer to wider market acceptance on November 18 with news that the **Food and Drug Administration** had cleared reading of digital Progesterone Receptor (PR) slides from a computer monitor using the digital pathology system of **Aperio Technologies, Inc.**, of Vista, California.

This endorsement is Aperio's second FDA clearance for diagnoses using digital slides. Last December, the FDA cleared Aperio's system to read digital HER2 slides from a computer monitor. The company (www.aperio.com) has an installed base of more than 450 systems in 28 countries. Lab users of this system include top-ranked hospitals, academic medical centers, and reference laboratories, along with a number of major pharmaceutical companies.

► **Equivalent to Glass Slides**

"Our FDA clearances for diagnosing digital HER2 and PR immunohistochemistry (IHC) slides on a computer monitor demonstrate that our digital pathology system is equivalent to diagnosing glass

IHC slides under a microscope," explained Aperio CEO Dirk Soenksen. "The system aids pathologists in detecting and measuring PR or HER2 by manual examination of the digital slide on a computer monitor.

"The specimen viewed is a formalin-fixed, paraffin-embedded normal and neoplastic tissue that has been immunohistochemically stained," noted Soenksen. "The image of that specimen is captured digitally and presented to the pathologist on the computer monitor."

Aperio's next goal is to pursue FDA clearance for diagnosing digital H&E slides. "We expect to submit an application to the FDA for clearance to market our system for the diagnosis of digital H&E breast cancer slides next year," predicted Soenksen.

Aperio believes that demand within the United States for digital pathology systems will increase dramatically when Aperio, and other manufacturers, can promote the use of digital slides for the most common types of pathology diagnoses. That belief is why the company is pursuing a series of FDA clearances, each of which will permit a pathologist to diagnose specimens digitized by an FDA-cleared system on a computer monitor.

In January, 2008, Aperio gained its first FDA clearance for the diagnosis of HER2 digital slide images from a computer monitor. Last month came Aperio's second FDA clearance, for use of its digital pathology system for the diagnosis of PR digital slide images from a computer monitor. Next year, in 2009, Aperio wants to file to obtain an FDA clearance that will allow its system to be used to diagnose H&E digital slides from a computer monitor.

While Aperio is the first and only company to receive FDA clearance for a system that can be used for making diagnoses from digital slides for clinical use in pathology, these FDA clearances are important to the wider pathology community. Each clearance establishes a precedent that makes it easier for other companies to submit digital pathology systems to the FDA and obtain clearance to market those systems for clinical applications.

From that perspective, Aperio's FDA clearances are opening a path for other companies to follow as they seek regulatory approval for their digital pathology systems. In turn, easier regulatory clearances will encourage research centers and other companies to develop and introduce a greater number of digital pathology products.

"The challenge for manufacturers is that digital pathology systems cannot be marketed for specific clinical applications without FDA approval," noted Soenksen. "Having FDA clearances makes it possible for manufacturers to legally promote the newly-cleared clinical uses of a digital pathology system.

► Looking Five Years Ahead

"If you look forward five years, everyone marketing digital pathology solutions will have these clearances," he added. "That's what happened in radiology. Some pioneering radiology imaging companies obtained the first required FDA clearances and other companies followed.

"Also, as the FDA clears specific applications of digital pathology systems for diagnosis from a digital slide image on a

computer monitor, more pathologists may consider other ways in which they could use this technology for what is called an 'off label use,'" he added.

"Pathologists may use digital pathology systems any way they like, so long as their laboratory properly validates that use under CLIA guidelines," said Soenksen. "That is why FDA clearances for our HER2 and PR diagnosis applications broaden the comfort zone for existing pathology customers to use digital pathology system 'off label'—that is, for applications that are similar to those that have been cleared. Should we obtain an FDA clearance for diagnosis of digital H&E breast tissue slides, it is conceivable that pathologists would be comfortable self-validating digital pathology for applications such as lung and prostate cancer.

► Acceptance Outside U.S.

"In fact, outside the United States, there is broader acceptance for pathologists to use digital pathology systems for clinical applications," Soenksen said. "In Canada, pathologists report their use of this technology for remote diagnosis. In Toronto, for example, it allows pathologists to consult on cases at a hospital 400 miles away." (See *TDR*, July 7, 2008.)

"The question is no longer whether digital technology is good enough for diagnosis," he said. "Already, manufacturers' efforts to obtain regulatory clearances lag behind the acceptance and use of digital pathology for diagnosis by respected labs in many countries across the globe. The question now is how long will it be until, within the United States, there is wider self-validated use of this technology for other areas of pathology beyond PR and HER2 testing for breast cancer."

These FDA clearances are one reason why pathologists and practice administrators should keep a watchful eye on the digital pathology imaging marketplace. Digital pathology is advancing swiftly. **TDR**

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