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Sectra and Leica Biosystems Receive FDA Clearance for Using DICOM Images in Pathology Diagnostics

International medical imaging IT and Cybersecurity company Sectra's digital pathology solution together with Leica Biosystems, Imaging, Inc.'s Aperio GT 450 DX have received a 510(k) clearance by the US Food & Drug Administration (FDA). This is the first time an FDA clearance within digital pathology allows the use of DICOM images for pathology diagnostics, which marks a significant step towards standardization in this field.

Sectra received its first FDA clearance during the pandemic, in 2020. The pandemic made the need and value of remote work even in the field of pathology obvious and has helped boost the adoption of digital pathology in the US. Today, the value of accessing, sharing and reviewing digital images is clear and the market for digital pathology in the US, as well as other countries, is growing rapidly.

"Given the rigorous review and clearance process leading up to this point, I see the new FDA clearance as strong proof of the quality of our solution. It is also an enabler for pathology departments to benefit from the latest scanner technology as well as the standardization that is happening within digital pathology. We have already seen how our customers utilize digital pathology to improve patient care, especially in complex cases such as cancer, and I am proud to be part of that journey," says Elin Kindberg, Global Product Manager Pathology at Sectra.

The FDA clearance includes:

- Sectra's digital pathology solution when used with Leica Biosystems Aperio GT 450 DX
- SVS and DICOM file formats
- Sectra UniView and IDS7
- cloud-based and on-premises installation

"Sectra has a strong track record of promoting and enabling open integrations and of pushing the development towards standardization within medical imaging IT. The recent FDA clearance including the clearance to utilize DICOM images for pathology diagnostics therefore makes me very proud. Due to the unique nature of the images used in digital pathology, proprietary formats have previously dominated. This FDA approval, including DICOM, shows that standardization is possible also within pathology. This is an important first step to a reality where healthcare providers can start reaping the benefits of a larger degree of freedom in choosing what hardware and software to combine, within pathology. This has the potential to increase workflow efficiency, facilitate the adoption of new technology and in the end—benefit patient care," says Dr. Torbjörn Kronander, CEO and President Sectra AB.

A digital pathology solution provides instant and, if necessary, remote access to digital images of tissue samples instead of relying on physical glass slides reviewed in microscopes. This optimizes the workflows for pathologists, leading to enhanced efficiency in cancer diagnostics. Learn more about Sectra's digital pathology solution >>

The pathology solution is part of Sectra's enterprise imaging solution, which provides a unified strategy for all imaging needs while lowering operational costs. The scalable and modular solution, with a VNA at its core, allows healthcare providers to grow from ology to ology and from enterprise to enterprise. Visit Sectra's website to read more about Sectra and why it's top-ranked in "Best in KLAS".

Source & Image Credit: Sectra

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