FDA CLEARANCE—SECTRA’S DIGITAL PATHOLOGY SOLUTION AVAILABLE FOR PRIMARY DIAGNOSTICS AND REMOTE READING IN THE U.S.

Shelton, CT – April 1, 2020 – International medical imaging IT and cybersecurity company Sectra (STO: SECT B) has received a 510(k) clearance by the US Food & Drug Administration (FDA). The clearance applies for Sectra Digital Pathology Module, the key component of Sectra’s pathology solution, when used together with Leica Biosystems’ scanner AT2 DX. This enables US healthcare providers to use Sectra’s digital pathology solution for primary diagnostics. The solution makes it possible to move towards fully integrated diagnostics, which is especially important in complex cancer cases.

“I’m excited that with the FDA approval, we are now able to offer US healthcare providers a digital pathology offering with a proven track-record of use for full-scale primary diagnostics and large volumes,” says Mikael Anden, President, Sectra Inc. “Our solution makes it possible for pathologists across the country to continue their important work from home without the need for a microscope. We look forward to providing uninterrupted pathology reading in these challenging times. This approval is an exciting and important step forward for pathology and cancer care in the US.”

Sectra’s digital pathology solution is already used in the US for research and tumor boards and can now also be used in primary diagnostics. With digital images of tissue samples instead of physical glass slides, pathologists gain instant access to current and historical images and related data as well as digital tools for reviewing the images. Digital access also facilitates efficient second opinions, remote reading, specialist consultations and makes integrated diagnostics possible.

The digital pathology solution is a component of Sectra’s enterprise imaging offering, of which all components are built on the same technical platform. This allows healthcare providers to use a single solution for their medical imaging needs across all specialties, enabling integrated diagnostics. A deeper cooperation and ability to access other departmental images and information contributes to improved efficiency and patient care. This is especially important for complex cases where both radiology and pathology play key roles. Instant access to digital pathology images, side by side with radiology or other images, enables more efficient discussions and the ability to give detailed descriptions of findings.

“Pathology is the next huge digitization of healthcare. The use of glass slides limits growth in today’s increasingly digital environment, especially in consolidated health care systems where potential synergies cannot be reached unless pathology is digitized. Our solution
opens up new opportunities in the US where we can point to our successes in Europe in large production centers,” says Dr. Torbjörn Kronander, President and CEO of Sectra.

Watch this video to learn more about how digital pathology can enable increased efficiency and higher precision for the pathologists.

About Sectra Imaging IT Solutions
With more than 30 years of innovation and approaching 2,000 installations worldwide, Sectra is a leading global provider of imaging IT solutions that support healthcare in achieving patient-centric care. Sectra offers an enterprise imaging solution comprising PACS for imaging-intense departments (radiology, pathology, cardiology, orthopedics), VNA, and share and collaborate solutions. Read more about Sectra and why Sectra PACS is “Best in KLAS” at https://medical.sectra.com/.