

Indica Labs Receives FDA Clearance for HALO AP Dx Digital Pathology Platform for Use with Hamamatsu Images Acquired with the NanoZoomer® S360MD Slide Scanner

Bridgewater, New Jersey – May 22, 2024 –Indica Labs, an industry leader in AI-powered digital pathology solutions, and Hamamatsu Photonics K.K., a pioneer in whole slide imaging systems, announce that the U.S. Food and Drug Administration (FDA) has issued a 510(k) clearance to Indica Labs for [HALO AP Dx](#), an enterprise digital pathology platform. HALO AP Dx is indicated for primary diagnosis of surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue scanned by the NanoZoomer® S360MD Slide scanner¹. This 510(k) clearance from the FDA expands on an established partnership between Indica Labs and Hamamatsu Photonics K.K.

Steven Hashagen, founder and CEO of Indica Labs said, "This FDA clearance for primary diagnosis of surgical pathology slides prepared from FFPE tissue is a significant milestone for HALO AP Dx that builds upon our prior CE-IVDR certification for HALO AP®. We're proud that our collaboration with Hamamatsu allowed us to leverage images from their NanoZoomer Slide scanner and led directly to this landmark achievement that will provide value to patients and healthcare providers alike."

HALO AP® is a case-centric digital pathology platform that is deployed worldwide and has transformed the way pathologists and researchers analyze, manage, and utilize digital pathology images through its comprehensive suite of tools and features for efficient and accurate image evaluation, management, and collaboration. HALO AP® and Hamamatsu NanoZoomer Slide scanners are already in use together at a variety of institutions and centers in the US for research purposes, and in the EU and the UK for clinical applications. In the US, Indica Labs will continue to offer HALO AP® for Research Use Only applications, and will now also offer HALO AP Dx for primary diagnosis of surgical pathology slides prepared from FFPE tissue.

The NanoZoomer® S360MD Slide scanner system is an expertly crafted digital pathology solution that displays images and provides image management tools and aids qualified pathologists in the review and interpretation of digital images of surgical pathology slides prepared from FFPE tissue.

Fumio Iwase, Executive Officer, Division Director, Systems Division at Hamamatsu Photonics K.K. said, "We believe that comprehensive tools are key to the advancement of digital pathology. The 510(k) clearance of the Indica Labs HALO AP Dx for review of images acquired with the previously 510(k)-cleared NanoZoomer® S360MD Slide scanner system is a testament to the unwavering quality and confidence that both partners consistently deliver to our valued customers. This regulatory achievement represents a significant stride forward, underscoring our joint commitment to providing cutting-edge solutions that elevate standards in the digital pathology field and empower professionals in their diagnostic endeavors."

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¹HALO AP Dx (K232833) is FDA-cleared for primary diagnostic use with the Hamamatsu NanoZoomer® S360MD Slide scanner in the US. In addition, HALO AP Dx provides built-in compliance and certifications with FDA 21 CFR Part 11 and HIPAA.

HALO AP® is CE-IVDR marked for in-vitro diagnostic use in Europe, the UK, and Switzerland. HALO AP is For Research Use Only in the US and is not FDA cleared for clinical diagnostic use. In addition, HALO AP provides built-in compliance and certifications with FDA 21 CFR Part 11, HIPAA, and GDPR.

About Indica Labs

Indica Labs is the world's leading provider of AI-powered digital pathology software and services. Our flagship [HALO®](#) and [HALO AI platform](#) powers quantitative evaluation of digital pathology images. [HALO Link](#) facilitates research-focused image management and collaboration while [HALO AP®](#) and [HALO AP Dx](#) deliver enterprise digital pathology for primary diagnosis with regulatory clearances in multiple markets. Through a commitment to open pathology and a combination of performance, scalability, and usability, our software solutions enable pharma companies, diagnostic labs, hospitals, research organizations, and Indica's own contract [Pharma Services](#) team to advance tissue-based research, clinical trials, and diagnostics.

About Hamamatsu Corporation

Hamamatsu Corporation is the North American subsidiary of Hamamatsu Photonics K.K. (Japan), a leading manufacturer of devices for the generation and measurement of infrared, visible, and ultraviolet light. These devices include photodiodes, silicon photomultipliers, photomultiplier tubes, scientific light sources, infrared detectors, image sensors, spectrometers, and cameras. The parent company is dedicated to the advancement of photonics through extensive research. This corporate philosophy results in state-of-the-art products which are used throughout the world in scientific, industrial, and commercial applications.

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