FDA News Release

FDA allows marketing of first whole slide imaging system for digital pathology

For Immediate Release

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Release

The U.S. Food and Drug Administration today permitted marketing of the Philips IntelliSite Pathology Solution (PIPS), the first whole slide imaging (WSI) system that allows for review and interpretation of digital surgical pathology slides prepared from biopsied tissue. This is the first time the FDA has permitted the marketing of a WSI system for these purposes.

“The system enables pathologists to read tissue slides digitally in order to make diagnoses, rather than looking directly at a tissue sample mounted on a glass slide under a conventional light microscope,” said Alberto Gutierrez, Ph.D., Director of the Office of In Vitro Diagnostics and Radiological Health in the FDA’s Center for Devices and Radiological Health. “Because the system digitizes slides that would otherwise be stored in physical files, it also provides a streamlined slide storage and retrieval system that may ultimately help make critical health information available to pathologists, other health care professionals and patients faster.”

Pathologists are medical doctors who specialize in understanding the cause and development of a disease or condition. In pathology, biopsied tissues are mounted onto glass slides and stained for viewing and evaluation. The PIPS uses proprietary hardware and software to scan and digitize conventional surgical pathology glass slides prepared from biopsied tissue at resolutions equivalent to 400 times magnification. These digitized images can then be reviewed and interpreted by pathologists.

The FDA reviewed the data for the PIPS through the de novo premarket review pathway, a regulatory pathway for devices of a new type with low- to moderate-risk that are not substantially equivalent to an already legally marketed device. The FDA evaluated data from a clinical study of approximately 2,000 surgical pathology cases using tissue from multiple parts of the body (anatomic sites). Results of the study found that clinical interpretations (diagnoses) made based on the PIPS images were comparable to those made using glass slides.

In this authorization, the FDA is establishing special controls that must be met to assure the digital imaging system’s precision, reliability, and clinical relevance. The risks associated with use of this technology are similar to that of the use of conventional light microscopy. These special controls are necessary to provide reasonable assurance of safety and effectiveness for this digital imaging system.

The FDA permitted marketing of the Philips IntelliSite Pathology Solution to Philips Medical Systems Nederland B.V.

The FDA, an agency within the U.S. Department of Health and Human Services, promotes and protects the public health by, among other things, assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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