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**SCHOOL OF MEDICINE**

**Department of Pathology & Immunology**  
**Division of Anatomic and Molecular Pathology**  
**John D. Pfeifer, M.D., Ph.D.**

October 5, 2009

Louise Magruder  
Center for Devices and Radiological Health (HFZ-440)  
FDA  
2098 Gaither Road  
Rockville, MD 20850

Dear Ms. Magruder:

I am writing to offer my perspective on the potential for digital pathology devices to be used as diagnostic instruments to assist pathologists in the evaluation of histopathology tissue samples in a manner equivalent to the traditional light microscope. I am aware that several companies have already filed for and received FDA clearance for image analysis applications related to immunohistochemical evaluation of digital slide images, however clearances regarding primary diagnoses have yet to be issued. The lack of such clearances is long overdue; I view the approval of digital pathology devices for diagnostic purposes as an avenue for enhancing patient care by improving the timeliness of diagnosis and consultation.

I am an American Board of Pathology-certified surgical pathologist in the Department of Pathology and Immunology at Washington University School of Medicine. I have over twenty years of experience in the field of diagnostic surgical pathology, and have been among the leaders in our Department's integration of digital pathology into our clinical practice and research activities. While I have experience with Aperio's hardware and software for digital analysis (as both a customer and collaborator for software upgrades), my experience in digital pathology is in no way limited to products provided by Aperio. Within our Department, we also have digital imaging systems manufactured by Trestle and by Biolumigene, which I have also used extensively.

In my experience, digital pathology provides an opportunity to produce an electronic slide record equivalent to a traditional histologic section on a glass slide. The image quality and associated software produce a virtual environment in which evaluation of histomorphology is similar to that of traditional light microscopy. However, digital pathology devices do more than merely duplicate existing diagnostic paradigms; in the appropriate settings, they provide added value to the practice of surgical pathology apart from their strict use in diagnosis. In our own practice, we use digital images to provide a permanent electronic record of glass slides that are not expected to permanently reside in our slide file (for example, for cases sent to us in consultation, and cases we send to outside institutions), to provide a permanent record of tissue sections that will be destroyed by ancillary testing (for example, by destaining and restaining, or by nucleic acid extraction for molecular diagnostic testing), and to make histologic sections available for immediate review (for example, in the frozen section area or for conferences eliminating time-consuming trips to slide storage areas which inevitably produce delays in diagnosis that can negatively impact patient care).

In closing, I would like to express my appreciation to the FDA for considering my views on such an important matter. Please do not hesitate to call me should you need additional information.

Sincerely,

John D. Pfeifer, MD, PhD  
Professor of Pathology and Immunology  
Professor of Obstetrics and Gynecology

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