The Clinical Outlook for AI in Pathology

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CLINICAL OUTLOOK

APPROVAL OF AI FOR PATHOLOGY DECISION SUPPORT

Product Classification

Software algorithm device to assist users in digital pathology (21 CFR Part 864.3750)

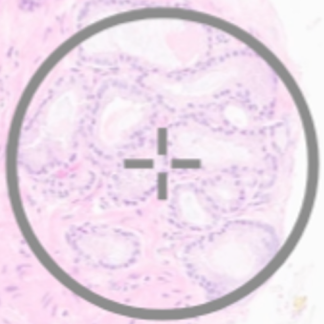
- A software algorithm device to assist users in digital pathology is an in vitro diagnostic device intended to evaluate acquired scanned pathology whole slide images. ***The device uses software algorithms to provide information to the user about presence, location, and characteristics of areas of the image with clinical implications***. Information from this device is intended to assist the user in determining a pathology diagnosis.

- Broad device classification
- Can apply to an array of AI tools for digital pathology
- Establishes the predicate for other approvals (regular 510(k) rather than de novo

CLINICAL OUTLOOK

APPROVAL OF AI – MEANING FOR OUR INDUSTRY

- Enables confident use of AI-based devices that help pathologists arrive at the correct diagnosis
- Ensures that AI generalizes across practice settings and laboratory variables
- Creates a path for clearances of future products in the category
- Sets a quality bar for future products
- Interoperability exists but is limited to FDA-cleared devices (scanner, viewer, monitor)
- Even within FDA cleared devices, each compatibility expansion effort would require 510(k) premarket review
- FDA intends to enforce regulations rigorously



CLINICAL OUTLOOK

APPROVAL OF AI – MEANING FOR PATHOLOGISTS

- Clinical-grade AI has been defined as an aid to pathologists
- Added scrutiny on slides provide pathologists greater confidence in their diagnoses
- Pathologists can focus their attention on the most critical aspects of establishing the diagnosis
- Compatibility responsibility is with the manufacturer
- Quality control rests with the manufacturer
- Unmodified use will scale easily among sites
- Verification much simpler, compared with LDT
- Cleared devices are “locked down” and require FDA review upon modification
- Modifications to the end-to-end test will require an LDT for the specific modification

CLINICAL OUTLOOK
WHERE ARE WE HEADED?

- Development of additional pathology decision support AI for defined use cases
- Process established to validate algorithms and ensure generalizability
- FDA clearance will establish “clinical grade” quality and ease implementation for users
- Increasing availability of decision support AI across pathology will help motivate transition to digital pathology
- Increased use of digital pathology opens the door for more advanced computational tools, such as digital biomarkers and multimodal data analytics