Decision Summaries and Paige Prostate

Peter J. Yang, PhD, RAC
De Novo Program Lead

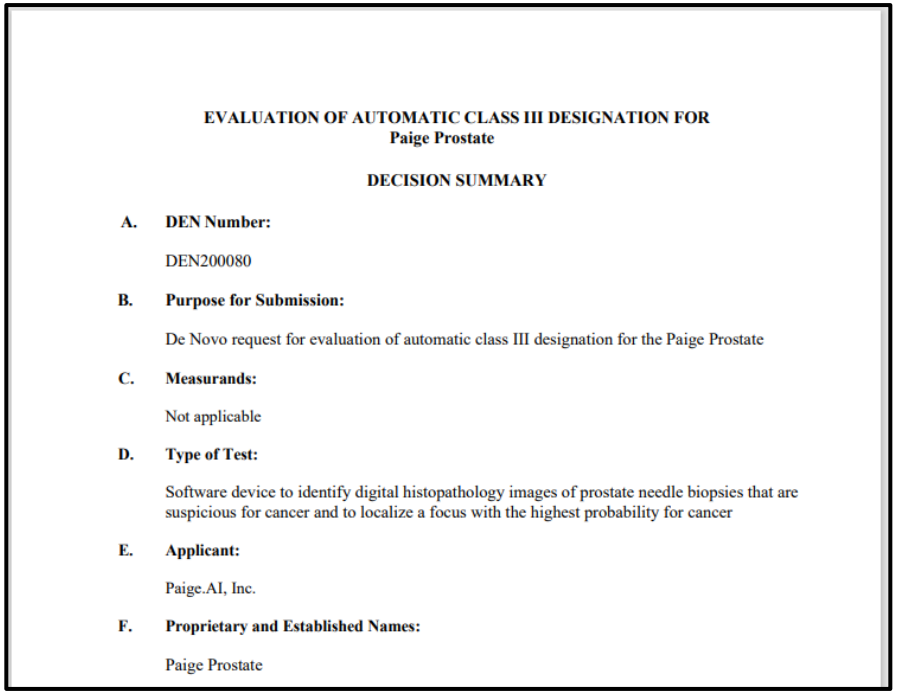
Office of Regulatory Programs (ORP)
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health
Food and Drug Administration

What Are We Talking About Here?

- FDA assures the safety and effectiveness of medical devices, including many in vitro diagnostics (IVDs) for use in pathology.
- FDA adopts a risk-based classification process to support predictable and least burdensome requirements for the data needed for FDA to permit marketing of medical devices.
- FDA is committed to transparency in decision making to foster innovation.
- Transparency for FDA's decision making for the Paige Prostate device is found in a **Decision Summary** document.
- I provide programmatic and regulatory oversight for devices reviewed through the "**De Novo request**" regulatory pathway, a common pathway to market for many novel types of devices.

Paige Prostate Decision Summary

- Search for “FDA” and “Medical Device Databases”
- Search the De Novo database for Paige Prostate and click on the Decision Summary link
- https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN200080.pdf



EVALUATION OF AUTOMATIC CLASS III DESIGNATION FOR
Paige Prostate

DECISION SUMMARY

A. DEN Number:

DEN200080

B. Purpose for Submission:

De Novo request for evaluation of automatic class III designation for the Paige Prostate

C. Measurands:

Not applicable

D. Type of Test:

Software device to identify digital histopathology images of prostate needle biopsies that are suspicious for cancer and to localize a focus with the highest probability for cancer

E. Applicant:

Paige.AI, Inc.

F. Proprietary and Established Names:

Paige Prostate

Decision Summaries

- Decision summary formats depend on submission type
  - 510(k) premarket notifications: 510(k) Summary
  - De Novo requests: De Novo Decision Summary
  - Premarket approvals: Summary of Safety and Effectiveness Data (SSED)
- Purpose of decision summary:
  - Provide transparency into FDA's decision making
  - Serve as comparison and reference for future submissions

Premarket Submissions to FDA

510(k) Premarket Notification

- **Existing** devices with existing technologies
- Provide robust data to demonstrate the device is as safe and effective as other similar devices (called "substantial equivalence")

De Novo Request

- **Novel** devices
- Provide robust data so FDA can determine that general and special controls (i.e., certain legal requirements) provide "reasonable assurance of safety and effectiveness"
- If granted, future devices are then reviewed through the 510(k) process

Broad Regulation Designed to Enable Pathology Innovation

- 21 CFR 864.3750 **Software algorithm device to assist users in digital pathology.** 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.

Special Controls (Class II)

- Special controls are legal requirements for all devices in the regulation and are written into the new classification regulation
- Special controls include:
  - Non-clinical (analytical) validation requirements
  - Clinical validation requirements
  - Labeling requirements
- **The De Novo device must meet its own special controls**

De Novo Decision Summary

- The Decision Summary, combined with the De Novo granting letter, tells FDA's risk-based classification "story"
  - New regulation (number, name, and identification)
  - Risk/mitigation table
  - Special controls (if class II)
  - Device description
  - Non-clinical and clinical data summaries
  - Benefit-risk discussion
- Demonstrates how special controls were met
- Serves as reference to support future 510(k) submissions

Decision Summaries for AI

- Ideally, a Decision Summary should discuss:
  - The general overview of AI model development
  - The dataset that was used to train the model
  - The validation process and dataset (separate and distinct) that was used to validate the model for real-world use
  - Any warnings, precautions, or limitations for using the AI software
  - Any information needed for ensuring correct use, including inputs and processing

How to Use A Decision Summary

- Read the Decision Summary and seek to:
  - Understand what the sponsor needed to do to get their device granted/cleared/approved
  - Understand how the sponsor met the special controls for the device type (if any) and what risks FDA is trying to address by requiring certain information
  - Align your own testing strategy to meet FDA's requirements
  - Assemble a testing strategy document for FDA to review in the context of a Pre-Submission (recommended)

Peter J. Yang, PhD, RAC
De Novo Program Lead
Office of Regulatory Programs (ORP)
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
Peter.Yang@fda.hhs.gov


FDA
U.S. FOOD & DRUG
ADMINISTRATION