SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K242783

B Applicant

Ventana Medical Systems, Inc.

C Proprietary and Established Names

Roche Digital Pathology Dx

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PSY	Class II	21 CFR 864.3700 - Whole Slide Imaging System	PA - Pathology

II Review Summary:

This 510(k) submission contains information/data on modifications made to the submitter's own CLASS II device requiring 510(k). The following items are present and acceptable.

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.

2. Submitter's statement that the **INDICATIONS FOR USE/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device, specifically the Image Acquisition Unit (IAU), **has not changed. This change is for adding a new model of the slide scanner component which has increased slide capacity,**

VENTANA DP 600 slide scanner, to the Roche Digital Pathology Dx [previously known as Roche Digital Pathology Dx (VENTANA DP 200) under K232879] system. As a part of the system modification, the system name is being changed to "Roche Digital Pathology Dx".

4. Comparison Information (i.e., similarities and differences) to the submitter's legally marketed predicate device including, labeling, intended use, and physical characteristics.

5. Detailed technical documentation to show the following items to demonstrate that the pixel pipelines are identical between VENTANA DP 600 slide scanner and the VENTANA DP200 slide scanner:

    a) Definition of the IAU, the collection of all components related to the pixel pipeline, including all electrical, optical, mechanical, and digital (software/firmware) components.

    b) Description of the boundary of the IAU, including how the IAU interacts with the remaining parts of the scanner via any electrical, optical, mechanical, and digital interfaces.

    c) List of the components that are not included in the IAU, to exhibit the differences between the two scanners. Both items #a) and #c) constituted all components needed in either scanner.

    d) Description and justification that the pixel pipeline is not affected by any component in item #c).

6. A Design Control Activities Summary which includes:

    a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.

    b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared device.