

**K061613 VENTANA IMAGE ANALYSIS SYSTEM - PATHWAY
HER2 (4B5)**Jan 10, 2007
215 days to decisionK061613 · Product code: **NQN** · Pathology
Source: <https://www.510kdatabase.net/k061613/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Microscope, Automated, Image Analysis, Immunohistochemistry,operator Intervention,nuclear Intensity & Percent Positivity (NQN)
Date received	Jun 9, 2006
Decision date	Jan 10, 2007
Days to decision	215 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Tripath Imaging
Location	Durham, NC, US
Contact	BRYAN J TUCKER
510(k) history	1 submissions · 1 cleared · 2007-2007

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