FDA 510(k) Premarket Notification

K053520 VENTANA IMAGE ANALYSIS SYSTEM, MODEL KI-67

CLEARED

Apr 11, 2006
113 days to decision

K053520 · Product code: **NQN** · Pathology
Source: https://www.510kdatabase.net/k053520/

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	Dec 19, 2005
Decision date	Apr 11, 2006
Days to decision	113 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Tripath Imaging, Inc.**
Location	Burlington, NC, US
Contact	BRYAN J TUCKER
510(k) history	4 submissions · 4 cleared · 2005-2006

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k053520/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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