

K050012 VENTANA IMAGE ANALYSIS SYSTEM

May 6, 2005
 123 days to decision

K050012 · Product code: **NQN** · Pathology
 Source: <https://www.510kdatabase.net/k050012/>

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	Jan 3, 2005
Decision date	May 6, 2005
Days to decision	123 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k050012/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026