

K043519 ARIOL HER-2/NEU FISHApr 25, 2005
126 days to decisionK043519 · Product code: **NTH** · Pathology
Source: <https://www.510kdatabase.net/k043519/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Automated Scanning Microscope And Image Analysis For Fluorescence In Situ Hybridization (fish) Assays (NTH)
Date received	Dec 20, 2004
Decision date	Apr 25, 2005
Days to decision	126 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Applied Imaging Corp.
Location	Santa Clara, CA, US
Contact	DIANE C DAY
510(k) history	7 submissions · 7 cleared · 1990-2005

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