

K101291 SCANVIEW HER2/NEU FISH SYSTEMNov 23, 2010
200 days to decisionK101291 · Product code: **NTH** · Pathology
Source: <https://www.510kdatabase.net/k101291/>**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	May 7, 2010
Decision date	Nov 23, 2010
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Applied Spectral Imaging , Ltd.
Location	Rayon, Ananna 43373, IL
Contact	DAN LAOR
510(k) history	7 submissions · 7 cleared · 1997-2015

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