

K092333 PATHIAM SYSTEM WITH ISCAN FOR P53 AND KI-67Oct 27, 2010
449 days to decisionK092333 · Product code: **NQN** · Pathology
Source: <https://www.510kdatabase.net/k092333/>**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	Aug 4, 2009
Decision date	Oct 27, 2010
Days to decision	449 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bioimagine, Inc.
Location	Cupertino, CA, US
Contact	INDU P LAKSHMAN
510(k) history	3 submissions · 3 cleared · 2007-2010

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