

**K080909 ICONOSCOPE ONCOFISH HER2 TEST SYSTEM,  
MODEL 2000**Oct 17, 2008  
199 days to decisionK080909 · Product code: **NTH** · Pathology  
Source: <https://www.510kdatabase.net/k080909/>**SUBMISSION DETAILS**

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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	Apr 1, 2008
Decision date	Oct 17, 2008
Days to decision	199 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ikonisys, Inc.</b>
Location	New Haven, CT, US
Contact	SYED ATAULLAH
510(k) history	4 submissions · 4 cleared · 2006-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080909/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026