

K962166 ORIGEN ANALYZERJul 31, 1996
57 days to decisionK962166 · Product code: **JJQ** · Chemistry
Source: <https://www.510kdatabase.net/k962166/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimeter, Photometer, Spectrophotometer For Clinical Use (JJQ)
Date received	Jun 4, 1996
Decision date	Jul 31, 1996
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Igen, Inc.
Location	Gaithersburg, MD, US
Contact	RICHARD PYTELEWSKI
510(k) history	1 submissions · 1 cleared · 1996-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k962166/> 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 July 1, 2026