

K140198 IMDX HSV-1/2 FOR ABBOTT M2000May 13, 2014
106 days to decisionK140198 · Product code: **OQO** · Microbiology
Source: <https://www.510kdatabase.net/k140198/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Herpes Simplex Virus Nucleic Acid Amplification Assay (OQO)
Date received	Jan 27, 2014
Decision date	May 13, 2014
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Intelligent Medical Devices, Inc.
Location	Beverly, MA, US
Contact	FRAN WHITE
510(k) history	4 submissions · 4 cleared · 2013-2014

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