

K111951 ISOAMP HSV ASSAYSep 27, 2011
81 days to decisionK111951 · Product code: **OQO** · Microbiology
Source: <https://www.510kdatabase.net/k111951/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Herpes Simplex Virus Nucleic Acid Amplification Assay (OQO)
Date received	Jul 8, 2011
Decision date	Sep 27, 2011
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biohelix Corporation
Location	Beverly, MA, US
Contact	FRAN WHITE
510(k) history	1 submissions · 1 cleared · 2011-2011

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