

**K103798 BD PROBETEC HERPES SIMPLEX VIRUSES (HSV 1&2) Q AMPLIFIED DNA ASSAYS**Mar 18, 2011  
81 days to decisionK103798 · Product code: **OQO** · Microbiology  
Source: <https://www.510kdatabase.net/k103798/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Herpes Simplex Virus Nucleic Acid Amplification Assay (OQO)
Date received	Dec 27, 2010
Decision date	Mar 18, 2011
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Becton, Dickinson &amp; CO</b>
Location	Franklin Lakes, NJ, US
Contact	Thalia Charles
510(k) history	190 submissions · 190 cleared · 2001-2016

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103798/> 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 May 24, 2026