

K140029 AMIPLIVUE HSV 1&2 ASSAYMar 26, 2014
79 days to decisionK140029 · Product code: **OQO** · Microbiology
Source: <https://www.510kdatabase.net/k140029/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Herpes Simplex Virus Nucleic Acid Amplification Assay (OQO) |
| Date received | Jan 6, 2014 |
| Decision date | Mar 26, 2014 |
| Days to decision | 79 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Quidel Corporation |
| Location | San Diego, CA, US |
| Contact | Ronald H Lollar |
| 510(k) history | 37 submissions · 35 cleared · 2010-2024 |

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