

K173376 ASI EvolutionJun 14, 2018
227 days to decisionK173376 · Product code: **GMQ** · Microbiology
Source: <https://www.510kdatabase.net/k173376/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antigens, Nontreponemal, All (GMQ) |
| Date received | Oct 30, 2017 |
| Decision date | Jun 14, 2018 |
| Days to decision | 227 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Arlington Scientific, Inc. (Asi) |
| Location | Springville, UT, US |
| Contact | David Binks |
| 510(k) history | 3 submissions · 3 cleared · 2018-2020 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173376/> 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 June 23, 2026