

**K973780 PERSONAL LUBRICATING LIQUID**Nov 26, 1997  
54 days to decisionK973780 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k973780/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Condom (HIS)                       |
| Date received         | Oct 3, 1997                        |
| Decision date         | Nov 26, 1997                       |
| Days to decision      | 54 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Qualis, Inc.</b>                   |
| Location       | Des Moines, IA, US                    |
| Contact        | MARY A FINN                           |
| 510(k) history | 6 submissions · 6 cleared · 1997-2005 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973780/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026