

K050212 PERSONAL WARMING JELLYMar 17, 2005
45 days to decisionK050212 · Product code: **NUC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k050212/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Jan 31, 2005
Decision date	Mar 17, 2005
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Qualis, Inc.
Location	Des Moines, IA, US
Contact	MIKE PETERSON
510(k) history	6 submissions · 6 cleared · 1997-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050212/> 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 29, 2026