

**K050211 PERSONAL WARMING GEL**Mar 17, 2005  
45 days to decisionK050211 · Product code: **NUC** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k050211/>**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	<b>Qualis, Inc.</b>
Location	Des Moines, IA, US
Contact	MIKE PETERSON
510(k) history	6 submissions · 6 cleared · 1997-2005

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050211/> 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