

**K021978 PETIT SOPHIA**Apr 8, 2003  
295 days to decisionK021978 · Product code: **LHD** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k021978/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Fertility Diagnostic, Proceptive (LHD)
Date received	Jun 17, 2002
Decision date	Apr 8, 2003
Days to decision	295 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nishitomo Co., Inc.</b>
Location	Japan, JP
Contact	LLOYD DUPLANTIS
510(k) history	2 submissions · 2 cleared · 1990-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k021978/> 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