

K162511 LELO RESPECT HEX Natural Rubber Latex CondomJan 13, 2017
127 days to decisionK162511 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k162511/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Condom (HIS)
Date received	Sep 8, 2016
Decision date	Jan 13, 2017
Days to decision	127 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Lelo, Inc.
Location	San Jose, CA, US
Contact	PAVLE SEDIC
510(k) history	3 submissions · 3 cleared · 2016-2025

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