

K160644 Lelo Hex Natural Rubber Latex CondomJun 30, 2016
115 days to decisionK160644 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k160644/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Mar 7, 2016
Decision date	Jun 30, 2016
Days to decision	115 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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