

K160399 Skyn Original Polyisoprene Lubricated Male CondomJul 25, 2016
164 days to decisionK160399 · Product code: **MOL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k160399/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom, Synthetic (MOL)
Date received	Feb 12, 2016
Decision date	Jul 25, 2016
Days to decision	164 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ansell Healthcare Products, LLC
Location	Dothan, AL, US
Contact	Robert Mahler
510(k) history	26 submissions · 26 cleared · 2005-2023

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