

**K132597 BLACK COLOURED CONDOM**Nov 25, 2013  
98 days to decisionK132597 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k132597/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Aug 19, 2013
Decision date	Nov 25, 2013
Days to decision	98 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Karex Industries Sdn. Bhd.</b>
Location	Pontian Kecil, Jalan Johor, MY
Contact	MARY GOH YIN
510(k) history	8 submissions · 8 cleared · 2007-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132597/> 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 May 27, 2026