

**K081886 KAREX INDUSTRIES MALE NATURAL RUBBER  
LATEX CONDOM, NON-SPERMICIDAL, LUBRICATED AND NON  
LUBRICATED**Feb 6, 2009  
219 days to decisionK081886 · Product code: **HIS** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k081886/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Jul 2, 2008
Decision date	Feb 6, 2009
Days to decision	219 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Karex Industries Sdn. Bhd.</b>
Location	Pontian Kecil, Jalan Johor, MY
Contact	LENG KIAN GOH
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/k081886/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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