

**K120555 LATEX MALE CONDOM (SMOOTH SURFACE) LATEX MALE CONDOM (TEXTURED SURFACE)**

Nov 2, 2012  
253 days to decision

K120555 · Product code: **HIS** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k120555/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Feb 23, 2012
Decision date	Nov 2, 2012
Days to decision	253 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Medical-Latex (Dua) Sdn. Bhd</b>
Location	Senai, MY
Contact	UMA DEVI
510(k) history	1 submissions · 1 cleared · 2012-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k120555/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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