

**K993395 REMED MALE LATEX CONDOM (DOUBLE WHOOPER)  
PREVENTOR, LUCKY BOY AND SUMMIT**Feb 15, 2000  
130 days to decisionK993395 · Product code: **HIS** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k993395/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Oct 8, 1999
Decision date	Feb 15, 2000
Days to decision	130 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Remed Pharma</b>
Location	Crofton, MD, US
Contact	E.J. Smith
510(k) history	9 submissions · 9 cleared · 2000-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k993395/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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