

**K993409 REMED MALE TUTTI FRUTTI CONDOM (COCONUT)
PREVENTOR, LUCKY BOY, SUMMIT**

Aug 18, 2000
315 days to decision

K993409 · Product code: **HIS** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k993409/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Oct 8, 1999
Decision date	Aug 18, 2000
Days to decision	315 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k993409/>; Data sourced from FDA 510(k) public records (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. - Generated June 29, 2026