FDA 510(k) Premarket Notification

K993404 REMED MALE LATEX CONDOM (CLASSIC) PREVENTOR, LUCKY BOY, AND SUMMIT

CLEARED

Feb 15, 2000
130 days to decision

K993404 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k993404/

SUBMISSION DETAILS

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

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