FDA 510(k) Premarket Notification

K983380 DUREX LUBRAGEL LATEX CONDOM

CLEARED

Nov 16, 1998
52 days to decision

K983380 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k983380/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Sep 25, 1998
Decision date	Nov 16, 1998
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**London Intl., LLC**
Location	Dothan, AL, US
Contact	NEIL ANDERSON
510(k) history	6 submissions · 6 cleared · 1998-1998