FDA 510(k) Premarket Notification

K032227 DUREX FLAVORED LATEX CONDOM

CLEARED

Mar 29, 2004
252 days to decision

K032227 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k032227/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Jul 21, 2003
Decision date	Mar 29, 2004
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ssl Americas, Inc.**
Location	Norcross, GA, US
Contact	KATHLEEN HARRIS
510(k) history	10 submissions · 10 cleared · 2002-2008