FDA 510(k) Premarket Notification

K970633 TUSTEX FLAVORED CONDOMS

CLEARED

Mar 21, 1997
29 days to decision

K970633 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k970633/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Feb 20, 1997
Decision date	Mar 21, 1997
Days to decision	29 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Line One Laboratories**
Location	Los Angeles, CA, US
Contact	ROBERT GRUBER
510(k) history	5 submissions · 5 cleared · 1997-1999