FDA 510(k) Premarket Notification

K953583 LUBRICATED CONDOM

CLEARED

Jan 26, 1996
178 days to decision

K953583 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k953583/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Aug 1, 1995
Decision date	Jan 26, 1996
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tactyl Technologies, Inc.**
Location	Vista, CA, US
Contact	JORGE HAIDER
510(k) history	7 submissions · 7 cleared · 1990-1996