FDA 510(k) Premarket Notification

K001212 TROJAN EXTRA LARGE LATEX CONDOM

CLEARED

May 9, 2000
25 days to decision

K001212 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k001212/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Condom (HIS)
Date received	Apr 14, 2000
Decision date	May 9, 2000
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Armkel, LLC**
Location	Mchenry, IL, US
Contact	STEPHEN C KOLAKOWSKY
510(k) history	68 submissions · 68 cleared · 1979-2004