FDA 510(k) Premarket Notification

K023176 UNDUS MALE LATEX CONDOM (WITH FLAVORING)

CLEARED

Dec 13, 2002
81 days to decision

K023176 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k023176/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Sep 23, 2002
Decision date	Dec 13, 2002
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Unidus Corp.**
Location	Seoul, Korea, KR
Contact	ELI J CARTER
510(k) history	7 submissions · 7 cleared · 1989-2007