FDA 510(k) Premarket Notification

K896142 RUBBER CONTRACEPTIVE (CONDOM)

CLEARED

Jun 6, 1990
225 days to decision

K896142 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k896142/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Oct 24, 1989
Decision date	Jun 6, 1990
Days to decision	225 days
Third-party review	No

APPLICANT

Company	**Guangzhou No. 11 Rubber Factory**
Location	Encinitas, CA, US
Contact	MARK S ROBINSON
510(k) history	1 submissions · 1 cleared · 1990-1990