FDA 510(k) Premarket Notification

K893217 LATEX PROPHYLACTIC/RUBBER CONTRACEPTIVE

CLEARED

Jan 10, 1990
258 days to decision

K893217 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k893217/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Apr 27, 1989
Decision date	Jan 10, 1990
Days to decision	258 days
Third-party review	No

APPLICANT

Company	**Shinhen Corp.**
Location	Los Angeles, CA, US
Contact	BNF ENTERPRISES
510(k) history	1 submissions · 1 cleared · 1990-1990

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k893217/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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