FDA 510(k) Premarket Notification

K822088 MALE CONDOM

CLEARED

Nov 3, 1982
113 days to decision

K822088 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k822088/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Jul 13, 1982
Decision date	Nov 3, 1982
Days to decision	113 days
Third-party review	No

APPLICANT

Company	**Schmid Laboratories, Inc.**
Location	Mchenry, IL, US
Contact	WAYNE MATELSKI
510(k) history	10 submissions · 9 cleared · 1980-1990