FDA 510(k) Premarket Notification

K874921 HEADFIRST (CONDOM)

CLEARED

May 13, 1988
162 days to decision

K874921 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k874921/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Dec 3, 1987
Decision date	May 13, 1988
Days to decision	162 days
Third-party review	No

APPLICANT

Company	**Stual Products, Inc.**
Location	Lindenhurst, NY, US
Contact	JAMES SCHISGALL
510(k) history	1 submissions · 1 cleared · 1988-1988