FDA 510(k) Premarket Notification

K881735 CONDOM

CLEARED

Jul 5, 1988
74 days to decision

K881735 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k881735/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Apr 22, 1988
Decision date	Jul 5, 1988
Days to decision	74 days
Third-party review	No

APPLICANT

Company	**Iris Medical Ent., Inc.**
Location	Washington, DC, US
Contact	LESLIE KUX
510(k) history	1 submissions · 1 cleared · 1988-1988