FDA 510(k) Premarket Notification

K900359 EMBRACE

CLEARED

Apr 2, 1990
67 days to decision

K900359 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k900359/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Jan 25, 1990
Decision date	Apr 2, 1990
Days to decision	67 days
Third-party review	No

APPLICANT

Company	**Safetex Corp.**
Location	Colonial Heights, VA, US
Contact	RONALD L DAVIS
510(k) history	7 submissions · 7 cleared · 1990-1993