FDA 510(k) Premarket Notification

K830691 PRIME

CLEARED

Mar 31, 1983
30 days to decision

K830691 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k830691/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Mar 1, 1983
Decision date	Mar 31, 1983
Days to decision	30 days
Third-party review	No

APPLICANT

Company	**Ansell, Inc.**
Location	Dothan, AL, US
510(k) history	30 submissions · 30 cleared · 1980-1999