

K830691 PRIMEMar 31, 1983
30 days to decisionK830691 · Product code: **HIS** · Obstetrics & GynecologySource: <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

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Device record: <https://www.510kdatabase.net/k830691/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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