FDA 510(k) Premarket Notification

K894489 GYNECOLOGIC EXAMINATION KIT

CLEARED

Oct 5, 1989
77 days to decision

K894489 · Product code: **HIB** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k894489/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Speculum, Vaginal, Nonmetal (HIB)
Date received	Jul 20, 1989
Decision date	Oct 5, 1989
Days to decision	77 days
Third-party review	No

APPLICANT

Company	**A & A Medical, Inc.**
Location	Branford, CT, US
Contact	CEDRIC K BERNBERG
510(k) history	23 submissions · 23 cleared · 1988-2001

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k894489/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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