FDA 510(k) Premarket Notification

K822084 PRO-SPEC

CLEARED

Aug 19, 1982
37 days to decision

K822084 · Product code: **HIB** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k822084/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Speculum, Vaginal, Nonmetal (HIB)
Date received	Jul 13, 1982
Decision date	Aug 19, 1982
Days to decision	37 days
Third-party review	No

APPLICANT

Company	**Exitec, Inc.**
Location	Mchenry, IL, US
510(k) history	4 submissions · 4 cleared · 1982-1983