FDA 510(k) Premarket Notification

K000444 MITYVIEW 4-WAY LATERAL EXPANDER SPECULUM

CLEARED

Apr 21, 2000
71 days to decision

K000444 · Product code: **HIB** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k000444/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Speculum, Vaginal, Nonmetal (HIB)
Date received	Feb 10, 2000
Decision date	Apr 21, 2000
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Prism Enterprises, Inc.**
Location	San Antonio, TX, US
Contact	JUDITH A HARBOUR
510(k) history	4 submissions · 4 cleared · 2000-2003