FDA 510(k) Premarket Notification

K002912 VAGINAL PORT, NON-STERILE / 600065, VAGINAL PORT, STERILE / 600073

CLEARED

Feb 21, 2001
156 days to decision

K002912 · Product code: **HIB** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k002912/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Speculum, Vaginal, Nonmetal (HIB)
Date received	Sep 18, 2000
Decision date	Feb 21, 2001
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sterinc**
Location	Santa Ana, CA, US
Contact	TODD ABRAHAM
510(k) history	1 submissions · 1 cleared · 2001-2001