FDA 510(k) Premarket Notification

K920187 FLEXIBLE SILICONE GELIHORN

CLEARED

Oct 23, 1992
283 days to decision

K920187 · Product code: **HHW** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k920187/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pessary, Vaginal (HHW)
Date received	Jan 14, 1992
Decision date	Oct 23, 1992
Days to decision	283 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Bioteque America, Inc.**
Location	Levittown, PA, US
Contact	DENIS DORSEY
510(k) history	10 submissions · 10 cleared · 1992-2004