FDA 510(k) Premarket Notification

K920633 PESSARY FLEXIBLE SILICONE NICHOLS

CLEARED

Nov 8, 1995
1365 days to decision

K920633 · Product code: **KXP** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k920633/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Vaginal (KXP)
Date received	Feb 12, 1992
Decision date	Nov 8, 1995
Days to decision	1365 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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