FDA 510(k) Premarket Notification

K983045 AMIELLE

CLEARED

Nov 25, 1998
85 days to decision

K983045 · Product code: **KXP** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k983045/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Vaginal (KXP)
Date received	Sep 1, 1998
Decision date	Nov 25, 1998
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Owen Mumford USA, Inc.**
Location	Marietta, GA, US
Contact	ROBERT E SHAW
510(k) history	10 submissions · 10 cleared · 1995-2001