FDA 510(k) Premarket Notification

K083769 MODIFICATION TO URESTA PESSARY

CLEARED

Jan 14, 2009
27 days to decision

K083769 · Product code: **HHW** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k083769/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pessary, Vaginal (HHW)
Date received	Dec 18, 2008
Decision date	Jan 14, 2009
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Eastmed, Inc.**
Location	Dundas, CA
Contact	ROSHANA AHMED
510(k) history	2 submissions · 2 cleared · 2008-2009