FDA 510(k) Premarket Notification

K061339 HIERSPEC SPECULUM

CLEARED

Sep 19, 2006
127 days to decision

K061339 · Product code: **HIB** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k061339/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Speculum, Vaginal, Nonmetal (HIB)
Date received	May 15, 2006
Decision date	Sep 19, 2006
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medical Products Div.**
Location	Indianapolis, IN, US
Contact	THOMAS W COPELAND
510(k) history	1 submissions · 1 cleared · 2006-2006