FDA 510(k) Premarket Notification

K130046 CLEARSPEC SINGLE USE VAGINAL SPECULUM

CLEARED

Aug 6, 2013
210 days to decision

K130046 · Product code: **HIB** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k130046/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Speculum, Vaginal, Nonmetal (HIB)
Date received	Jan 8, 2013
Decision date	Aug 6, 2013
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Clearspec, LLC**
Location	Herkimer, NY, US
Contact	IRA DUESLER
510(k) history	1 submissions · 1 cleared · 2013-2013

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k130046/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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