FDA 510(k) Premarket Notification

K143308 GelPOINT Transvaginal Access Platform

CLEARED

Oct 13, 2015
329 days to decision

K143308 · Product code: **HEW** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k143308/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Culdoscope (and Accessories) (HEW)
Date received	Nov 18, 2014
Decision date	Oct 13, 2015
Days to decision	329 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Applied Medical Resources**
Location	Launa Hills, CA, US
Contact	Frans VandenBroek
510(k) history	58 submissions · 58 cleared · 1992-2021