FDA 510(k) Premarket Notification

K052314 DYNAREX VAGINAL SPECULA 4900, MODELS 4911-SMALL, 4912-MEDIUM, 4913-LARGE

CLEARED

Nov 9, 2005
76 days to decision

K052314 · Product code: **HIB** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k052314/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Speculum, Vaginal, Nonmetal (HIB)
Date received	Aug 25, 2005
Decision date	Nov 9, 2005
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dynarex Corp.**
Location	Brewster, NY, US
Contact	JAMES HURLMAN
510(k) history	19 submissions · 18 cleared · 1986-2005