

**K052314 DYNAREX VAGINAL SPECULA 4900, MODELS  
4911-SMALL, 4912-MEDIUM, 4913-LARGE**Nov 9, 2005  
76 days to decisionK052314 · Product code: **HIB** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k052314/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k052314/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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