

K053583 OPTIVIA HYSTEROSCOPIC INTRODUCER, OPTIVIA STEERABLE WORKING CHANNELMar 31, 2006
98 days to decisionK053583 · Product code: **HIH** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k053583/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Dec 23, 2005
Decision date	Mar 31, 2006
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Optivia Medical, LLC
Location	Winston-Salem, NC, US
Contact	ROBERT M KELLEY
510(k) history	1 submissions · 1 cleared · 2006-2006

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