

**K970078 HYDROFLOEX HD HYSTEROSCOPIC DISTENTION SYSTEM**Dec 11, 1997  
336 days to decisionK970078 · Product code: **HIG** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k970078/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Hysteroscopic (HIG)
Date received	Jan 9, 1997
Decision date	Dec 11, 1997
Days to decision	336 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Davol Inc., Sub. C. R. Bard, Inc.</b>
Location	Canston, RI, US
Contact	ROBIN M DRAGO
510(k) history	24 submissions · 24 cleared · 1994-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970078/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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