

**K962482 SCUBA SYSTEM**Nov 1, 1996  
128 days to decisionK962482 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k962482/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Jun 26, 1996
Decision date	Nov 1, 1996
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gynecare, Inc.</b>
Location	Menlo Park, CA, US
Contact	MILTON B MCCOLL, M.D.
510(k) history	3 submissions · 3 cleared · 1996-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k962482/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026