

**K954488 ROLLER ELECTRODE**Mar 6, 1997  
526 days to decisionK954488 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k954488/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Sep 27, 1995
Decision date	Mar 6, 1997
Days to decision	526 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Olympus America, Inc.</b>
Location	Lake Success, NY, US
Contact	BARRY E SANDS
510(k) history	149 submissions · 149 cleared · 1994-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954488/> 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 May 18, 2026