

**K233500 Benesta Tissue Removal Device**Nov 30, 2023  
30 days to decisionK233500 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k233500/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Oct 31, 2023
Decision date	Nov 30, 2023
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Caldera Medical, Inc.</b>
Location	Agoura Hills, CA, US
Contact	Vicki Gail
510(k) history	22 submissions · 22 cleared · 2006-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233500/> 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 14, 2026