

K253020 Strauss Surgical Resection InstrumentsJun 4, 2026
258 days to decisionK253020 · Product code: **HIH** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k253020/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hysteroscope (and Accessories) (HIH)
Date received	Sep 19, 2025
Decision date	Jun 4, 2026
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	American Medical Endoscopy, Inc.
Location	Doral, FL, US
Contact	Matthew Schwimmer
510(k) history	3 submissions · 3 cleared · 2025-2026

REGULATORY CONSULTANT

Consulting firm	Medical Device Academy, Inc.
Contact	Rob Packard

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253020/> Data sourced from FDA 510(k) public records (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. - Generated June 9, 2026