

**K251652 Strauss Surgical Cystoscopes & Hysteroscopes
 (STS-2040-302ASA HD-endoscope, STS-2040-302AA HD-
 endoscope, STS-2040-302BA HD-endoscope, STS-2040-302BSA
 HD-endoscope, STS-2040-302ESA HD-endoscope,
 STS-2040-302CA HD-endoscope, STS-2029-302AA HD-
 endoscope, STS-2029-302BA HD-endoscope, STS-2040-298DSA-
 RWF-endoscope, STS-2040-298ASA-RWF-endoscope,
 STS-2040-300GSA-RWF-endoscope, STS-2040-303CA-RWF-
 endoscope, STS-2040-280ASA-OLY-endoscope,
 STS-2040-280ESA-OLY-endoscope, STS-2040-283BSA-OLY-
 endo**

Aug 1, 2025
 64 days to decision

K251652 · Product code: **FAJ** · Obstetrics & Gynecology
 Source: <https://www.510kdatabase.net/k251652/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	May 29, 2025
Decision date	Aug 1, 2025
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	American Medical Endoscopy, Inc.
Location	Doral, FL, US
Contact	Matthew Schwimmer
510(k) history	2 submissions · 2 cleared · 2025-2026

REGULATORY CONSULTANT

Consulting firm	Medical Device Academy, Inc.
Contact	Shaily Shah

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)