

**K253892 Strauss Surgical Cystoscopes & Hysteroscopes
(STS-2040-302ASA HD-endoscope, 4 x 302 mm, view. Dir. 0°,
standard, autoclavable)**Apr 16, 2026
133 days to decisionK253892 · Product code: **FAJ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k253892/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Dec 4, 2025
Decision date	Apr 16, 2026
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302AA HD-endoscope, 4 x 302 mm, view. Dir. 0°, wide angle, autoclavable); Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302BA HD-endoscope, 4 x 302 mm, view. Dir. 30°, wide angle, autoclavable); Strauss Surgical Cystoscopes & Hysteroscopes (STS-2040-302BSA HD-endoscope, 4 x 302 mm, view. Dir. 30°,

APPLICANT

Company	Strauss Surgical USA
Location	Doral, FL, US
Contact	Antonio Nava
510(k) history	1 submissions · 1 cleared · 2026-2026

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)

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