

K201355 Endomat Select, IBS Shaver Software, LicenseJul 22, 2020
62 days to decisionK201355 · Product code: **HIG** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k201355/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Insufflator, Hysteroscopic (HIG)
Date received	May 21, 2020
Decision date	Jul 22, 2020
Days to decision	62 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Karl Storz SE & CO. KG
Location	Tuttlingen, DE
Contact	Alexey Davidov
Website	https://www.karlstorz.com
510(k) history	23 submissions · 23 cleared · 2018-2026

Karl Storz SE & CO. KG is a medical device manufacturer headquartered in Tuttlingen, Germany. The company specializes in endoscopic instruments and visualization systems for surgical and diagnostic procedures. The company has received FDA 510(k) clearances from total submissions since 2018. Karl Storz devices span multiple surgical specialties, with particular strength in Gastroenterology & Urology applications. The latest FDA 510(k) clearance was granted in 2026, confirming the company's active regulatory engagement. Recent cleared devices include flexible video endoscop...

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Device record: <https://www.510kdatabase.net/k201355/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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