

**K031895 KSEA OPSERVER LAP**Sep 23, 2003  
96 days to decisionK031895 · Product code: **FET** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k031895/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Video Imaging System/component, Gastroenterology-urology (FET)
Date received	Jun 19, 2003
Decision date	Sep 23, 2003
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>KARL STORZ Endoscopy-America, Inc.</b>
Location	Mchenry, IL, US
Contact	JAMES A LEE
510(k) history	361 submissions · 361 cleared · 1980-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031895/> 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 15, 2026