

K946330 KARL STORTZ PIVOT ARM LAPAROSCOPE SLEEVE, ENDO-RETRACTOR

Feb 6, 1995
39 days to decision

K946330 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k946330/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Dec 29, 1994
Decision date	Feb 6, 1995
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	KARL STORZ Endoscopy-America, Inc.
Location	Mchenry, IL, US
Contact	MARIKA ANDERSON
510(k) history	361 submissions · 361 cleared · 1980-2024

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Device record: <https://www.510kdatabase.net/k946330/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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