

K161112 KARL STORZ Flexible Video-Neuro-Endoscope SystemSep 17, 2016
150 days to decisionK161112 · Product code: **GWG** · Neurology
Source: <https://www.510kdatabase.net/k161112/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Endoscope, Neurological (GWG) |
| Date received | Apr 20, 2016 |
| Decision date | Sep 17, 2016 |
| Days to decision | 150 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161112/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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