

K093054 SCALP DURA RETRACTOR, MODEL KS00474Nov 15, 2010
411 days to decisionK093054 · Product code: **GZT** · Neurology
Source: <https://www.510kdatabase.net/k093054/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Retractor, Self-retaining, For Neurosurgery (GZT) |
| Date received | Sep 30, 2009 |
| Decision date | Nov 15, 2010 |
| Days to decision | 411 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k093054/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026