

K160369 GuideWireMar 10, 2016
29 days to decisionK160369 · Product code: **PGW** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k160369/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Ear, Nose, And Throat Stereotaxic Instrument (PGW) |
| Date received | Feb 10, 2016 |
| Decision date | Mar 10, 2016 |
| Days to decision | 29 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Fiagon GmbH |
| Location | Hennigsdorf, DE |
| Contact | Dirk Mucha |
| 510(k) history | 15 submissions · 15 cleared · 2014-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160369/> 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 26, 2026