

**K161853 proGAV Programmable Shunt System, proGAV 2.0
Adjustable Shunt System, proSA Adjustable Shunt System**Feb 27, 2017
236 days to decisionK161853 · Product code: **JXG** · Neurology
Source: <https://www.510kdatabase.net/k161853/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Shunt, Central Nervous System And Components (JXG) |
| Date received | Jul 6, 2016 |
| Decision date | Feb 27, 2017 |
| Days to decision | 236 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Aesculap, Inc. |
| Location | Burlingame, CA, US |
| Contact | KATHY A. RACOSKY |
| 510(k) history | 207 submissions · 201 cleared · 1991-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161853/> 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 June 1, 2026