

K212641 StrataMR II Valves and ShuntsSep 16, 2021
27 days to decisionK212641 · Product code: **JXG** · Neurology
Source: <https://www.510kdatabase.net/k212641/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Shunt, Central Nervous System And Components (JXG) |
| Date received | Aug 20, 2021 |
| Decision date | Sep 16, 2021 |
| Days to decision | 27 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Medtronic Neurosurgery |
| Location | Goleta, CA, US |
| Contact | Swara Vashi |
| 510(k) history | 28 submissions · 27 cleared · 2001-2025 |

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