

K183515 MR8 Drill System, Midas Rex MR8 ClearView ToolsMay 12, 2019
145 days to decisionK183515 · Product code: **HBC** · Neurology
Source: <https://www.510kdatabase.net/k183515/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Motor, Drill, Electric (HBC) |
| Date received | Dec 18, 2018 |
| Decision date | May 12, 2019 |
| Days to decision | 145 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Medtronic Powered Surgical Solutions |
| Location | Fort Worth, TX, US |
| Contact | Jenna Groves |
| 510(k) history | 9 submissions · 9 cleared · 2007-2021 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183515/> 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