

K003535 STYLET KIT, MODELS 6254,6282,6293Feb 8, 2001
84 days to decisionK003535 · Product code: **DRB** · CardiovascularSource: <https://www.510kdatabase.net/k003535/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stylet, Catheter (DRB) |
| Date received | Nov 16, 2000 |
| Decision date | Feb 8, 2001 |
| Days to decision | 84 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Medtronic Vascular |
| Location | Walker, MI, US |
| Contact | KAREN CLEMENT |
| 510(k) history | 475 submissions · 453 cleared · 1977-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003535/> 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