

K001927 VECTRA (TM) VASCULAR ACCESS GRAFT-5MM DIAMETER,6MM DIAMETER AND VECTRA (TM) VASCULAR ACCESS GRAFT FOR REVISION-5MM DIAME

Dec 18, 2000
175 days to decision

K001927 · Product code: **DSY** · Cardiovascular
Source: <https://www.510kdatabase.net/k001927/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY) |
| Date received | Jun 26, 2000 |
| Decision date | Dec 18, 2000 |
| Days to decision | 175 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Thoratec Laboratories Corp. |
| Location | Walker, MI, US |
| Contact | DONALD A MIDDLEBROOK |
| 510(k) history | 10 submissions · 9 cleared · 1978-2000 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k001927/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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