

K953870 ACTTRAC ELECTRONIC CONTROL DEVICE FOR THE ACT & ACT II COAGULATION INSTRUMENTS

Oct 31, 1995
75 days to decision

K953870 · Product code: **GKN** · Hematology
Source: <https://www.510kdatabase.net/k953870/>

SUBMISSION DETAILS

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Timer, Clot, Automated (GKN) |
| Date received | Aug 17, 1995 |
| Decision date | Oct 31, 1995 |
| Days to decision | 75 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k953870/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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