

K160091 Temperature Probe, Affinity Temperature ProbeMay 20, 2016
126 days to decisionK160091 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k160091/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Continuous Measurement Thermometer (FLL) |
| Date received | Jan 15, 2016 |
| Decision date | May 20, 2016 |
| Days to decision | 126 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Medtronic, Inc. |
| Location | Mounds View, MN, US |
| Contact | Choua Thao |
| Website | https://www.medtronic.com |
| 510(k) history | 209 submissions · 208 cleared · 1981-2026 |

Medtronic, Inc. is a global medical device manufacturer headquartered in Mounds View, United States. The company develops and markets a broad range of medical devices across multiple therapeutic areas. Medtronic maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1981. The company specializes primarily in Cardiovascular devices, which represent 82% of its submission portfolio. Recent clearances include coronary perfusion cannulae, intracoronary shunts, venous cannulae, guidewires, deflectable catheter systems,...

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