FDA 510(k) Premarket Notification

# K864853 OMNI THERM TEMPERATURE MONITOR

**CLEARED**

Feb 4, 1987
55 days to decision

K864853 · Product code: **KPD** · General Hospital
Source: https://www.510kdatabase.net/k864853/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Strip, Temperature, Forehead, Liquid Crystal (KPD) |
| Date received | Dec 11, 1986 |
| Decision date | Feb 4, 1987 |
| Days to decision | 55 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Omni Therm, Inc.** |
| Location | St. Louis, MO, US |
| Contact | DALE E WALTERS |
| 510(k) history | 5 submissions · 4 cleared · 1987-1996 |