

K884160 OHMEDA - OHIO(R) 3500 INFANT WARMER SYSTEMNov 21, 1988
48 days to decisionK884160 · Product code: **FMT** · General Hospital
Source: <https://www.510kdatabase.net/k884160/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Warmer, Infant Radiant (FMT) |
| Date received | Oct 4, 1988 |
| Decision date | Nov 21, 1988 |
| Days to decision | 48 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Ohmeda Medical |
| Location | Madison, WI, US |
| Contact | F PROFUMO |
| 510(k) history | 120 submissions · 118 cleared · 1984-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k884160/>, 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