

**K912280 BI-TEMP TEMPERATURE MONITOR, MODEL TM-400D**Oct 17, 1991  
147 days to decisionK912280 · Product code: **FLL** · General Hospital  
Source: <https://www.510kdatabase.net/k912280/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	May 23, 1991
Decision date	Oct 17, 1991
Days to decision	147 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Respiratory Support Products, Inc.</b>
Location	Mchenry, IL, US
Contact	GORDON SHIGEZAWA
510(k) history	27 submissions · 26 cleared · 1979-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k912280/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026