

**K030580 SURETEMP PLUS**May 6, 2003  
71 days to decisionK030580 · Product code: **FLL** · General Hospital  
Source: <https://www.510kdatabase.net/k030580/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Continuous Measurement Thermometer (FLL) |
| Date received         | Feb 24, 2003                             |
| Decision date         | May 6, 2003                              |
| Days to decision      | 71 days                                  |
| Third-party review    | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Welch Allyn, Inc.</b>  |
| Location       | Mchenry, IL, US   |
| Contact        | DEBRA L JACKSON   |
| Website        | <a href="http://www.welchallyn.com/">http://www.welchallyn.com/</a> |
| 510(k) history | 111 submissions · 111 cleared · 1977-2025                           |

Welch Allyn, Inc. is a medical device manufacturer based in McHenry, US. The company specializes in patient monitoring and diagnostic equipment for healthcare settings. Welch Allyn has maintained a strong FDA 510(k) regulatory record since 1977. The company has received FDA 510(k) clearances from total submissions. Cardiovascular monitoring devices represent the dominant category in recent clearances, including the Connex vital signs monitor series and central station systems. The company's latest clearance in 2025 demonstrates continued regulatory activity and product in...

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