

**K122412 VISIOFOCUS**Mar 13, 2013  
217 days to decisionK122412 · Product code: **FLL** · General Hospital  
Source: <https://www.510kdatabase.net/k122412/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Special                                  |
| Device classification | Continuous Measurement Thermometer (FLL) |
| Date received         | Aug 8, 2012                              |
| Decision date         | Mar 13, 2013                             |
| Days to decision      | 217 days                                 |
| Third-party review    | No                                       |
| Summary / Statement   | Statement                                |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Tecnimed S.R.L.</b>                |
| Location       | Great Neck, NY, US                    |
| Contact        | Claude Berthoin                       |
| 510(k) history | 5 submissions · 4 cleared · 2004-2017 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122412/> 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 14, 2026