

**K160680 VisioFocus Mini, VisioFocus Smart**Apr 19, 2017  
405 days to decisionK160680 · Product code: **FLL** · General Hospital  
Source: <https://www.510kdatabase.net/k160680/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Mar 10, 2016
Decision date	Apr 19, 2017
Days to decision	405 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	Cinzia Bellifemine
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/k160680/> 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