

**K083419 ACTHERM DIGITAL CLINICAL THERMOMETER  
PROBE COVERS, MODEL(S) MEDACCU1010, MEDACCU1010-1,  
MEDACCU1020**Jul 16, 2009  
239 days to decisionK083419 · Product code: FLL · General Hospital  
Source: <https://www.510kdatabase.net/k083419/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Nov 19, 2008
Decision date	Jul 16, 2009
Days to decision	239 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Actherm, Inc.</b>
Location	Jubei, Hsinchu, TW
Contact	RICHARD HSIEH
510(k) history	8 submissions · 8 cleared · 2001-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083419/> 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 June 21, 2026