

K090031 ACTHERM INFRARED EAR THERMOMETER, ACT 8000 SERIES

Apr 16, 2009
101 days to decision

K090031 · Product code: FLL · General Hospital
Source: <https://www.510kdatabase.net/k090031/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Jan 5, 2009
Decision date	Apr 16, 2009
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary
Other names	PROBE COVER FOR ACTHERM INFRARED EAR THERMOMETER, MODEL MEDACCU2010

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k090031/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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