

K063418 ACON DIGITAL THERMOMETER PROBE COVERSFeb 2, 2007
81 days to decisionK063418 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k063418/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Nov 13, 2006
Decision date	Feb 2, 2007
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	ACON Laboratories, Inc.
Location	San Diego, CA, US
Contact	JINN-NAN LIN, PH.D
Website	http://www.aconlabs.com/
510(k) history	85 submissions · 85 cleared · 1998-2025

ACON Laboratories, Inc. is a global medical device manufacturer headquartered in San Diego, California. The company develops and manufactures diagnostic and point-of-care testing devices for hospitals, clinical laboratories, physician offices, blood banks, pharmacies, and veterinary clinics. ACON operates in over 130 countries and maintains FDA-registered manufacturing facilities with ISO 13485 certification. ACON has received FDA 510(k) clearances from total submissions since 1998, with no denied submissions. The company specializes in chemistry devices, including blood ...
