

K180298 welloStationXNov 30, 2018
301 days to decisionK180298 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k180298/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Feb 2, 2018
Decision date	Nov 30, 2018
Days to decision	301 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wello, Inc.
Location	Addison, TX, US
Contact	Alan Camerik(Rik) Heller
Website	http://www.welloinc.com
510(k) history	1 submissions · 1 cleared · 2018-2018

Wello, Inc. is a Texas-based medical device company specializing in precision temperature health systems. Designed and manufactured in Addison, the company develops innovative infection control solutions for healthcare facilities, manufacturing plants, and other industries. Wello's technology detects potential disease spreaders early, before symptoms appear. The company has received FDA 510(k) clearance from total submission. Its cleared device falls within the General Hospital category. The company's regulatory clearance was granted in 2018. Wello is currently inactive, ...

REGULATORY CONSULTANT

Consulting firm	Ken Block Consulting
Contact	Alan C Heller

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k180298/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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