FDA 510(k) Premarket Notification

K173194 Temperature Probe

CLEARED

Oct 10, 2018
373 days to decision

K173194 · Product code: **FLL** · General Hospital
Source: https://www.510kdatabase.net/k173194/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Oct 2, 2017
Decision date	Oct 10, 2018
Days to decision	373 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Orantech, Inc.**
Location	Shenzhen, CN
Contact	Hsin Xiong
510(k) history	5 submissions · 5 cleared · 2018-2019

REGULATORY CONSULTANT

Consulting firm	**Chonconn Medical Device Consulting Co., Ltd.**
Contact	Kevin Wang

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