

K203643 Sensatronic Reusable Temperature ProbesAug 11, 2021
240 days to decisionK203643 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k203643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Dec 14, 2020
Decision date	Aug 11, 2021
Days to decision	240 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sensatronic GmbH
Location	Wismar, DE
Contact	Jens Schwarz
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Imagenix, Inc.
Contact	Stephen H. Gorski

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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