FDA 510(k) Premarket Notification

K210924 e-Celsius Medical System

CLEARED

Jun 28, 2023
821 days to decision

K210924 · Product code: **FLL** · General Hospital
Source: https://www.510kdatabase.net/k210924/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Mar 29, 2021
Decision date	Jun 28, 2023
Days to decision	821 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Bodycap**
Location	Herouville Saint Clair, FR
Contact	Sébastien Moussay
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Arazy Group Consultants, Inc.**
Contact	Ray Kelly

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