FDA 510(k) Premarket Notification

CLEARED

K202306 T3 Platform software

Nov 25, 2020
103 days to decision

K202306 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k202306/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Aug 14, 2020
Decision date	Nov 25, 2020
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Etiometry, Inc.**
Location	Boston, MA, US
Contact	Tim Hanson
Website	https://www.etiometry.com
510(k) history	11 submissions · 11 cleared · 2015-2026

Etiometry, Inc. is a clinical decision-support software company founded in 2010. Based in Boston, the company develops AI-driven clinical intelligence platforms for intensive care settings. The platform aggregates patient data, provides risk analytics, automates clinical pathways, and supports quality improvement initiatives in high-acuity care environments. Etiometry has received FDA 510(k) clearances from total submissions since 2015. The company specializes exclusively in Cardiovascular devices and software solutions. The latest clearance in 2026 demonstrates continued...