FDA 510(k) Premarket Notification

K043010 HOLTER RECORDER H3+

CLEARED

Feb 25, 2005
116 days to decision

K043010 · Product code: **MWJ** · Cardiovascular
Source: https://www.510kdatabase.net/k043010/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Electrocardiograph, Ambulatory (without Analysis) (MWJ)
Date received	Nov 1, 2004
Decision date	Feb 25, 2005
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mortara Instrument, Inc.**
Location	Walker, MI, US
Contact	HARLAN L VAN MATRE
510(k) history	51 submissions · 51 cleared · 1983-2019