

K980619 SABRATEK PATIENT HOME MANAGEMENT SYSTEMAug 20, 1998
183 days to decisionK980619 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k980619/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Feb 18, 1998
Decision date	Aug 20, 1998
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sabratek Corp.
Location	Chicago, IL, US
Contact	EDWARD WADDELL
510(k) history	7 submissions · 7 cleared · 1992-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k980619/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 4, 2026