

K083828 SLEUTH AT IMPLANTABLE CARDIAC MONITORING SYSTEM -6 CM AND 8CM ANTENNA, PERSONAL DIAGNOSTICS MANAGER (PDM) ACCESSORY KITFeb 11, 2009
50 days to decisionK083828 · Product code: **MXC** · Cardiovascular
Source: <https://www.510kdatabase.net/k083828/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Recorder, Event, Implantable Cardiac, (without Arrhythmia Detection) (MXC)
Date received	Dec 23, 2008
Decision date	Feb 11, 2009
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Transoma
Location	St. Paul, MN, US
Contact	LISA STONE
510(k) history	1 submissions · 1 cleared · 2009-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083828/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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