

K091206 SLEUTH AT IMPLANTABLE CARDIAC MONITORING SYSTEM-6 AND 8CM ANTENNA, PERSONAL DIAGNOSTIC MANAGER(PDM) ACCESSORY KIT, MODELMay 18, 2009
24 days to decisionK091206 · Product code: **MXC** · Cardiovascular
Source: <https://www.510kdatabase.net/k091206/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Recorder, Event, Implantable Cardiac, (without Arrhythmia Detection) (MXC)
Date received	Apr 24, 2009
Decision date	May 18, 2009
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Transoma Medical
Location	Arden Hills, MN, US
Contact	LISA STONE
510(k) history	2 submissions · 2 cleared · 2007-2009

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