

**K073147 SLEUTH IMPLANTABLE ECG SYSTEM-8 CM  
ACCESSORY KIT, MODEL 3000-08**Dec 3, 2007  
25 days to decisionK073147 · Product code: **MXC** · Cardiovascular  
Source: <https://www.510kdatabase.net/k073147/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Recorder, Event, Implantable Cardiac, (without Arrhythmia Detection) (MXC)
Date received	Nov 8, 2007
Decision date	Dec 3, 2007
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k073147/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 23, 2026