

K063035 SLEUTH IMPLANTABLE ECG MONITORING SYSTEMOct 1, 2007
367 days to decisionK063035 · Product code: **MXC** · Cardiovascular
Source: <https://www.510kdatabase.net/k063035/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Event, Implantable Cardiac, (without Arrhythmia Detection) (MXC)
Date received	Sep 29, 2006
Decision date	Oct 1, 2007
Days to decision	367 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Transnoma Medical, Inc.
Location	Arden Hills, MN, US
Contact	ANGELA RAUN
510(k) history	1 submissions · 1 cleared · 2007-2007

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