

K002068 ORG-9200AFeb 8, 2001
216 days to decisionK002068 · Product code: **DSI** · Cardiovascular
Source: <https://www.510kdatabase.net/k002068/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Jul 7, 2000
Decision date	Feb 8, 2001
Days to decision	216 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nihon Kohden America, Inc.
Location	Foothill Ranch, CA, US
Contact	BONNIE BISHOP
510(k) history	166 submissions · 163 cleared · 1979-2012

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