

K152305 Nihon Kohden Afib Detection Program QP-039PApr 8, 2016
238 days to decisionK152305 · Product code: **DSI** · Cardiovascular
Source: <https://www.510kdatabase.net/k152305/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Aug 14, 2015
Decision date	Apr 8, 2016
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nihon Kohden Corporation
Location	Tokyo, JP
Contact	TOM BENTO
510(k) history	18 submissions · 18 cleared · 2015-2025

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