

K912744 ORG-8200A UNIVERSAL SIGNAL HOUSINGDec 9, 1991
171 days to decisionK912744 · Product code: **DSI** · Cardiovascular
Source: <https://www.510kdatabase.net/k912744/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Jun 21, 1991
Decision date	Dec 9, 1991
Days to decision	171 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k912744/> Data sourced from FDA 510(k) public records (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. - Generated May 24, 2026