FDA 510(k) Premarket Notification

K912744 ORG-8200A UNIVERSAL SIGNAL HOUSING

CLEARED

Dec 9, 1991
171 days to decision

K912744 · 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