FDA 510(k) Premarket Notification

K903514 FUKUDA DENSHI MODEL LX-3100

CLEARED

Jan 30, 1991
180 days to decision

K903514 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k903514/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Aug 3, 1990
Decision date	Jan 30, 1991
Days to decision	180 days
Third-party review	No

APPLICANT

Company	**Fukuda Denshi USA, Inc.**
Location	Mchenry, IL, US
Contact	ROBERT J STEURER
510(k) history	68 submissions · 68 cleared · 1984-2018