FDA 510(k) Premarket Notification

K903704 FUKUDA DENSHI MODEL FCP-2201 MODIFICATION

CLEARED

Sep 7, 1990
87 days to decision

K903704 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k903704/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Jun 12, 1990
Decision date	Sep 7, 1990
Days to decision	87 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