FDA 510(k) Premarket Notification

K893405 MODEL DS-504 DYNASCOPE PATIENT MONITOR

CLEARED

Oct 2, 1989
153 days to decision

K893405 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k893405/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	May 2, 1989
Decision date	Oct 2, 1989
Days to decision	153 days
Third-party review	No

APPLICANT

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