FDA 510(k) Premarket Notification

K840055 DYNASCOPE SERIES

CLEARED

Aug 22, 1984
229 days to decision

K840055 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k840055/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Jan 6, 1984
Decision date	Aug 22, 1984
Days to decision	229 days
Third-party review	No

APPLICANT

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