FDA 510(k) Premarket Notification

K833594 FUKUDA DENSHI FX-302 AUTO/THREE CHAN

CLEARED

Sep 11, 1984
335 days to decision

K833594 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k833594/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Oct 12, 1983
Decision date	Sep 11, 1984
Days to decision	335 days
Third-party review	No

APPLICANT

Company	**Brentwood Instruments, Inc.**
Location	Mchenry, IL, US
510(k) history	21 submissions · 20 cleared · 1981-1990