FDA 510(k) Premarket Notification

K813022 FUKUDA DENSHI CARDIMAX FK-12

CLEARED

Dec 2, 1981
36 days to decision

K813022 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k813022/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Oct 27, 1981
Decision date	Dec 2, 1981
Days to decision	36 days
Third-party review	No

APPLICANT

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