FDA 510(k) Premarket Notification

K012404 K-DEFIB/PACE ADULT ELECTRODE, MODEL KDP-85

CLEARED

Oct 12, 2001
74 days to decision

K012404 · Product code: **DRO** · Cardiovascular
Source: https://www.510kdatabase.net/k012404/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pacemaker, Cardiac, External Transcutaneous (non-invasive) (DRO)
Date received	Jul 30, 2001
Decision date	Oct 12, 2001
Days to decision	74 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Katecho, Inc.**
Location	Des Moines, IA, US
Contact	WARREN R WALTERS
510(k) history	26 submissions · 25 cleared · 1984-2001