FDA 510(k) Premarket Notification

K894356 DISP. POLYMER (HYDROGEL) EXTERNAL PACING & DEFIB.

CLEARED

Dec 13, 1989
152 days to decision

K894356 · Product code: **LDD** · Cardiovascular
Source: https://www.510kdatabase.net/k894356/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Jul 14, 1989
Decision date	Dec 13, 1989
Days to decision	152 days
Third-party review	No

APPLICANT

Company	**Phycon**
Location	Tampa, FL, US
Contact	C KLESSY
510(k) history	2 submissions · 2 cleared · 1989-1989