FDA 510(k) Premarket Notification

K941404 IMPULSE 4000 DEFIBRILLATOR/TRANSCUTANEOUS PACER ANALYZER

CLEARED

Jun 29, 1994
98 days to decision

K941404 · Product code: **DRL** · Cardiovascular
Source: https://www.510kdatabase.net/k941404/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tester, Defibrillator (DRL)
Date received	Mar 23, 1994
Decision date	Jun 29, 1994
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hogan & Hartson**
Location	Mchenry, IL, US
Contact	HOWARD M HOLSTEIN
510(k) history	26 submissions · 25 cleared · 1980-1998