FDA 510(k) Premarket Notification

K092913 EP-4TM CARDIAC STIMULATOR, MODELS: EP-04-02, EP-04-04

CLEARED

Oct 16, 2009
24 days to decision

K092913 · Product code: **JOQ** · Cardiovascular
Source: https://www.510kdatabase.net/k092913/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Generator, Pulse, Pacemaker, External Programmable (for Electrophysiological Studies Only) (JOQ)
Date received	Sep 22, 2009
Decision date	Oct 16, 2009
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ep Medsystems**
Location	West Berlin, NJ, US
Contact	SUSHMA RAO
510(k) history	12 submissions · 12 cleared · 1996-2009