FDA 510(k) Premarket Notification

K924891 PLEXUS PULSER I, PLEXUS PULSER II

CLEARED

Jun 7, 1993
252 days to decision

K924891 · Product code: **JOW** · Cardiovascular
Source: https://www.510kdatabase.net/k924891/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Sep 28, 1992
Decision date	Jun 7, 1993
Days to decision	252 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Dobre, Inc.**
Location	Mchenry, IL, US
Contact	ROMAN SZPUR
510(k) history	2 submissions · 2 cleared · 1977-1993