FDA 510(k) Premarket Notification

K012141 AECP-A, AUTOMATIC EXTERNAL COUNTERPULSATION DEVICE

CLEARED

Oct 25, 2001
107 days to decision

K012141 · Product code: **DRN** · Cardiovascular
Source: https://www.510kdatabase.net/k012141/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Counter-pulsating, External (DRN)
Date received	Jul 10, 2001
Decision date	Oct 25, 2001
Days to decision	107 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**External Counterpulsation Lab**
Location	Kfar Saba, IL
Contact	AHAVA STEIN
510(k) history	2 submissions · 2 cleared · 2001-2003