FDA 510(k) Premarket Notification

K032421 AMBU PEDIATRIC MULTI-FUNCTION DEFIBRILLATION ELECTRODE

CLEARED

Feb 27, 2004
206 days to decision

K032421 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k032421/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Aug 5, 2003
Decision date	Feb 27, 2004
Days to decision	206 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ambu, Inc.**
Location	Walker, MI, US
Contact	SANJAY PARIKH
510(k) history	33 submissions · 33 cleared · 1984-2005