FDA 510(k) Premarket Notification

CLEARED

K050413 AMPLIEF WRIST BLOOD PRESSURE MONITOR, MODEL M600

Mar 4, 2005
14 days to decision

K050413 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k050413/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Feb 18, 2005
Decision date	Mar 4, 2005
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Amplife Corporation**
Location	Great Neck, NY, US
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	4 submissions · 4 cleared · 2004-2005