FDA 510(k) Premarket Notification

CLEARED

K090768 FULLY AUTOMATIC ELECTRONIC BLOOD PRESSURE MONITOR, MODELS KD 5901, KD-7909,

Jun 4, 2009
73 days to decision

K090768 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k090768/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Mar 23, 2009
Decision date	Jun 4, 2009
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Andon Health Co, Ltd.**
Location	Tiajin, CN
Contact	LIU YI
510(k) history	92 submissions · 92 cleared · 2008-2025