FDA 510(k) Premarket Notification

K913523 AUTO. OSCILLOMETRIC DIGITAL BLOOD PRESS. MONITOR

CLEARED

Nov 6, 1991
90 days to decision

K913523 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k913523/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Aug 8, 1991
Decision date	Nov 6, 1991
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Omron Healthcare, Inc.**
Location	Vernon Hills, IL, US
Contact	LEE COBOT
510(k) history	68 submissions · 67 cleared · 1991-2024