FDA 510(k) Premarket Notification

K920778 OMRON WRIST DIGITAL BLOOD PRESSURE MONITOR HEM-601

CLEARED

Dec 24, 1992
308 days to decision

K920778 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k920778/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Feb 20, 1992
Decision date	Dec 24, 1992
Days to decision	308 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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