FDA 510(k) Premarket Notification

K202228 Omron Model BP7900 Blood Pressure Monitor + EKG

CLEARED

Apr 1, 2021
237 days to decision

K202228 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k202228/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Aug 7, 2020
Decision date	Apr 1, 2021
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Experien Group**
Contact	Kit Cariquitan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov