FDA 510(k) Premarket Notification

K894563 OMRON DIGITAL BLOOD PRESSURE MONITOR MODEL HEM814F

CLEARED

Mar 6, 1990
228 days to decision

K894563 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k894563/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jul 21, 1989
Decision date	Mar 6, 1990
Days to decision	228 days
Third-party review	No

APPLICANT

Company	**Omron Electronics, Inc.**
Location	Schaumburg, IL, US
Contact	OISHI
510(k) history	10 submissions · 10 cleared · 1987-1990