

**K894563 OMRON DIGITAL BLOOD PRESSURE MONITOR
MODEL HEM814F**Mar 6, 1990
228 days to decisionK894563 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k894563/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026