

**K061822 OMRON AUTOMATIC BLOOD PRESSURE MONITOR
WITH COMFIT CUFF, MODEL HEM 780 N3**Aug 2, 2006
35 days to decisionK061822 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k061822/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jun 28, 2006
Decision date	Aug 2, 2006
Days to decision	35 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061822/> 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 28, 2026