

**K001670 AUTOMATIC BLOOD PRESSURE MONITOR WITH INTELLISENSE, MODEL HEM-757**Jun 30, 2000  
29 days to decisionK001670 · Product code: **DXN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k001670/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jun 1, 2000
Decision date	Jun 30, 2000
Days to decision	29 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Omron Healthcare, Inc.</b>
Location	Vernon Hills, IL, US
Contact	OSAMU SHIRASAKI
510(k) history	68 submissions · 67 cleared · 1991-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001670/>. 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