

**K001671 ULTRA COMPACT WRIST BLOOD PRESSURE  
MONITOR WITH INTELLISENSE, MODEL HEM-630**Jun 30, 2000  
29 days to decisionK001671 · Product code: **DXN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k001671/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001671/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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