

**K050233 OMRON NON-INVASIVE BLOOD PRESSURE MONITOR  
WITH AUGMENTATION INDEX, MODEL HEM-9000AI**Oct 28, 2005  
269 days to decisionK050233 · Product code: **DXN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k050233/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Feb 1, 2005
Decision date	Oct 28, 2005
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Omron Healthcare, Inc.</b>
Location	Vernon Hills, IL, US
Contact	JIM LI, PH.D.
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/k050233/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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