

**K935462 OMBRON TWIN-HEAD MASSAGER MODEL HM-101**Mar 4, 1994  
112 days to decisionK935462 · Product code: **ISA** · Physical MedicineSource: <https://www.510kdatabase.net/k935462/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Therapeutic, Electric (ISA)
Date received	Nov 12, 1993
Decision date	Mar 4, 1994
Days to decision	112 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	FRANK BRICHETTO
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/k935462/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026