

**K833839 BIOTHERM**Dec 27, 1983  
54 days to decisionK833839 · Product code: **ILJ** · Physical MedicineSource: <https://www.510kdatabase.net/k833839/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bath, Hydro-massage (ILJ)
Date received	Nov 3, 1983
Decision date	Dec 27, 1983
Days to decision	54 days
Third-party review	No

**APPLICANT**

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Company	<b>Trileen, Inc.</b>
Location	Costa Mesa, CA, US
Contact	Frederic Ouweleen
510(k) history	2 submissions · 2 cleared · 1983-1983

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k833839/>; 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 July 1, 2026