

**K083662 CRITICOOL**Mar 26, 2009  
106 days to decisionK083662 · Product code: **DWJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k083662/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Dec 10, 2008
Decision date	Mar 26, 2009
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mtre Advanced Technology , Ltd.</b>
Location	Mccordsville, IN, US
Contact	IFAT OREN
510(k) history	6 submissions · 6 cleared · 2000-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083662/> 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 20, 2026