

K102112 CRITICOOL PRONov 18, 2010
113 days to decisionK102112 · Product code: **DWJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k102112/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Jul 28, 2010
Decision date	Nov 18, 2010
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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