

K124010 ACCUSONIC ADVANTAGEAug 23, 2013
239 days to decisionK124010 · Product code: **IMI** · Physical MedicineSource: <https://www.510kdatabase.net/k124010/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ultrasonic Diathermy For Use In Applying Therapeutic Deep Heat (IMI) |
| Date received | Dec 27, 2012 |
| Decision date | Aug 23, 2013 |
| Days to decision | 239 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|--|
| Company | Metron Medical Australia, Pty, Ltd. |
| Location | Carrum Downs, AU |
| Contact | DAVID MITCHELL |
| 510(k) history | 17 submissions · 17 cleared · 1999-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k124010/> Data sourced from FDA 510(k) public records (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. - Generated June 8, 2026