

K120470 MIPALJun 8, 2012
113 days to decisionK120470 · Product code: **DRG** · Cardiovascular
Source: <https://www.510kdatabase.net/k120470/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG) |
| Date received | Feb 16, 2012 |
| Decision date | Jun 8, 2012 |
| Days to decision | 113 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Watermark Medical |
| Location | Brookfield, WI, US |
| Contact | MICHAEL J LEIGH |
| 510(k) history | 3 submissions · 3 cleared · 2012-2017 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120470/> 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 May 24, 2026