

K910661 MODEL 205 SHOCK-TRODEMay 2, 1991
78 days to decisionK910661 · Product code: **DRO** · CardiovascularSource: <https://www.510kdatabase.net/k910661/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pacemaker, Cardiac, External Transcutaneous (non-invasive) (DRO) |
| Date received | Feb 13, 1991 |
| Decision date | May 2, 1991 |
| Days to decision | 78 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Cardiotronics, Inc. |
| Location | West Carlsbad, CA, US |
| Contact | TIM J WAY |
| 510(k) history | 27 submissions · 27 cleared · 1988-1995 |

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