

K051038 506 PATIENT MONITORAug 12, 2005
109 days to decisionK051038 · Product code: **DRT** · Cardiovascular
Source: <https://www.510kdatabase.net/k051038/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Cardiac (incl. Cardiometer & Rate Alarm) (DRT) |
| Date received | Apr 25, 2005 |
| Decision date | Aug 12, 2005 |
| Days to decision | 109 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Criticare Systems, Inc. |
| Location | Waukesha, WI, US |
| Contact | ALEX KAPLAN |
| 510(k) history | 1 submissions · 1 cleared · 2005-2005 |

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