

**K020456 EASI 12 LEAD ALGORITHM**Jul 9, 2002  
148 days to decisionK020456 · Product code: **DRW** · CardiovascularSource: <https://www.510kdatabase.net/k020456/>**SUBMISSION DETAILS**

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|                       |                                                   |
|-----------------------|---------------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Special                                           |
| Device classification | Adaptor, Lead Switching, Electrocardiograph (DRW) |
| Date received         | Feb 11, 2002                                      |
| Decision date         | Jul 9, 2002                                       |
| Days to decision      | 148 days                                          |
| Third-party review    | No                                                |
| Summary / Statement   | Summary                                           |

**APPLICANT**

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|                |                                           |
|----------------|-------------------------------------------|
| Company        | <b>Philips Medical Systems</b>            |
| Location       | Seattle, WA, US                           |
| Contact        | PAUL SCHRADER                             |
| 510(k) history | 107 submissions · 105 cleared · 2002-2021 |

Philips Medical Systems is a Dutch multinational health technology company headquartered in Amsterdam with U.S. operations based in Seattle. The company evolved from a consumer electronics conglomerate founded in 1891 to a healthcare-focused organization. Philips Medical Systems has received FDA 510(k) clearances from total submissions between 2002 and 2021. The company's regulatory focus centered on Cardiovascular devices, which represented 79% of all submissions. This historical record reflects the company's significant presence in diagnostic ultrasound systems and pati...