

K113144 PAGERWRITER TC 20, 30, 50, 70Apr 3, 2012
161 days to decisionK113144 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k113144/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrocardiograph (DPS) |
| Date received | Oct 25, 2011 |
| Decision date | Apr 3, 2012 |
| Days to decision | 161 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Philips Medical Systems |
| 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...