

K023440 PHILIPS DIGITAL IMAGING OPTION RELEASE 1Oct 30, 2002
15 days to decisionK023440 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k023440/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | Oct 15, 2002 |
| Decision date | Oct 30, 2002 |
| Days to decision | 15 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Philips Medical Systems |
| Location | Seattle, WA, US |
| Contact | LYNN HARMER |
| 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...