

K022618 X-SCRIBE IISep 6, 2002
30 days to decisionK022618 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k022618/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Electrocardiograph (DPS) |
| Date received | Aug 7, 2002 |
| Decision date | Sep 6, 2002 |
| Days to decision | 30 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Mortara Instrument, Inc. |
| Location | Walker, MI, US |
| Contact | HARLAN VAN MATRE |
| 510(k) history | 51 submissions · 51 cleared · 1983-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k022618/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 19, 2026