

**K990113 DISPOSABLE ECG MONITORING ELECTRODES,
MODELS 4500,4530, 4533, 4539, 4540, AND 4560**Dec 6, 1999
327 days to decisionK990113 · Product code: **DRX** · Cardiovascular
Source: <https://www.510kdatabase.net/k990113/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrode, Electrocardiograph (DRX) |
| Date received | Jan 13, 1999 |
| Decision date | Dec 6, 1999 |
| Days to decision | 327 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Maersk Medical A/S |
| Location | Sylmar, CA, US |
| Contact | RICHARD A HAMER |
| 510(k) history | 9 submissions · 9 cleared · 1998-2001 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k990113/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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