FDA 510(k) Premarket Notification

**CLEARED**

# K030431 MODIFICATION TO DASH 3000/4000 PATIENT MONITOR

Feb 26, 2003
16 days to decision

K030431 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k030431/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX) |
| Date received | Feb 10, 2003 |
| Decision date | Feb 26, 2003 |
| Days to decision | 16 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Ge Medical Systems Information Technologies** |
| Location | Mchenry, IL, US |
| Contact | KAREN M LUNDE |
| 510(k) history | 136 submissions · 132 cleared · 1978-2012 |