FDA 510(k) Premarket Notification

# K010923 KION ANAESTHESIA SYSTEM, MODEL 65 03 879 E392E

**CLEARED**

Jan 23, 2002
302 days to decision

K010923 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k010923/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX) |
| Date received | Mar 27, 2001 |
| Decision date | Jan 23, 2002 |
| Days to decision | 302 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Siemens Elema AB** |
| Location | Mchenry, IL, US |
| Contact | DIANE WURZBURGER |
| 510(k) history | 63 submissions · 60 cleared · 1978-2003 |