

**K093501 ELANCE VITAL SIGNS MONITOR AND ELANCE
CENTRAL STATION**

Nov 24, 2009
12 days to decision

K093501 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k093501/>

SUBMISSION DETAILS

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX) |
| Date received | Nov 12, 2009 |
| Decision date | Nov 24, 2009 |
| Days to decision | 12 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Spacelabs Medical, Inc. |
| Location | Hamden, CT, US |
| Contact | DAVID GERAGHTY |
| 510(k) history | 35 submissions · 34 cleared · 1993-2012 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k093501/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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