

K844940 SPACELABS MODEL 90201 HOLTER RECORDERFeb 14, 1985
56 days to decisionK844940 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k844940/>**SUBMISSION DETAILS**

| | |
|-----------------------|----------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Recorder, Magnetic Tape, Medical (DSH) |
| Date received | Dec 20, 1984 |
| Decision date | Feb 14, 1985 |
| Days to decision | 56 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------------------------------------------------------|
| Company | Spacelabs, Inc. |
| Location | Mchenry, IL, US |
| Contact | ALLEN M HANS |
| Website | https://www.spacelabshealthcare.com |
| 510(k) history | 46 submissions · 46 cleared · 1976-1996 |

Spacelabs, Inc. is a medical device company based in McHenry, US. The company specializes in patient monitoring and diagnostic cardiology solutions. Spacelabs received FDA 510(k) clearances from total submissions. The company's regulatory activity spans from 1976 to 1996, with Cardiovascular devices representing the dominant focus of its portfolio. This historical record reflects the company's early contributions to cardiac monitoring and anesthesiology device development. Notable cleared devices include multigas analyzers, capnograph modules, patient care management syst...

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