

K921216 OFF-LINE ANALYSIS SYSTEMNov 20, 1992
252 days to decisionK921216 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k921216/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Computer, Diagnostic, Programmable (DQK) |
| Date received | Mar 13, 1992 |
| Decision date | Nov 20, 1992 |
| Days to decision | 252 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Softheart, Inc. |
| Location | South Burlington, VT, US |
| Contact | HENRY A GELLER |
| 510(k) history | 3 submissions · 3 cleared · 1992-1993 |

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