FDA 510(k) Premarket Notification

# K771372 SYSTEM II

**CLEARED**

Aug 4, 1977
10 days to decision

K771372 · Product code: **DSF** · Cardiovascular
Source: https://www.510kdatabase.net/k771372/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Recorder, Paper Chart (DSF) |
| Date received | Jul 25, 1977 |
| Decision date | Aug 4, 1977 |
| Days to decision | 10 days |
| Third-party review | No |

## APPLICANT

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|---|---|
| Company | **Irex Corp.** |
| Location | Mchenry, IL, US |
| 510(k) history | 10 submissions · 10 cleared · 1977-1985 |