

K962983 STERILE SOFT-TEMPJan 10, 1997
162 days to decisionK962983 · Product code: **ILO** · Physical Medicine
Source: <https://www.510kdatabase.net/k962983/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pack, Hot Or Cold, Water Circulating (ILO) |
| Date received | Aug 1, 1996 |
| Decision date | Jan 10, 1997 |
| Days to decision | 162 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Adroit Medical Systems, Inc. |
| Location | Morganton, NC, US |
| Contact | RICHARD L STRUDER |
| 510(k) history | 6 submissions · 6 cleared · 1992-2008 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k962983/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 25, 2026