

K895100 ECHO GEL (RAINFOREST)Nov 3, 1989
80 days to decisionK895100 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k895100/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Transducer, Ultrasonic, Diagnostic (ITX) |
| Date received | Aug 15, 1989 |
| Decision date | Nov 3, 1989 |
| Days to decision | 80 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Lead-Lok, Inc. |
| Location | Sandpoint, ID, US |
| Contact | JAMES HEALY |
| 510(k) history | 5 submissions · 5 cleared · 1989-2001 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k895100/>; 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 May 21, 2026