

K950400 HAND MASSAGE UNITMar 30, 1995
57 days to decisionK950400 · Product code: **IRO** · Physical Medicine
Source: <https://www.510kdatabase.net/k950400/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Vibrator, Therapeutic (IRO) |
| Date received | Feb 1, 1995 |
| Decision date | Mar 30, 1995 |
| Days to decision | 57 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Ultrassage, Inc. |
| Location | Ville Mont-Royal, Quebec, CA |
| Contact | KEN KUPELIAN |
| 510(k) history | 2 submissions · 1 cleared · 1995-1995 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k950400/> 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 29, 2026