

K984199 EXONIXFeb 17, 1999
85 days to decisionK984199 · Product code: **IMI** · Physical MedicineSource: <https://www.510kdatabase.net/k984199/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ultrasonic Diathermy For Use In Applying Therapeutic Deep Heat (IMI)
Date received	Nov 24, 1998
Decision date	Feb 17, 1999
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Fibra Sonics, Inc.
Location	Walker, MI, US
Contact	ROBERT BROHM
510(k) history	10 submissions · 10 cleared · 1980-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k984199/> 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