

**K042619 ULTRABIO - IN VIVO BIOCOMPATIBLE,  
BIOELIMINATED STERILE ULTRASOUND IMAGING COUPLANT**

Nov 5, 2004  
42 days to decision

K042619 · Product code: MUI · Radiology  
Source: <https://www.510kdatabase.net/k042619/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Media, Coupling, Ultrasound (MUI)
Date received	Sep 24, 2004
Decision date	Nov 5, 2004
Days to decision	42 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Sonotech, Inc.</b>
Location	Bellingham, WA, US
Contact	MARGARET J LARSON
510(k) history	14 submissions · 14 cleared · 1995-2004

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k042619/> 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 18, 2026