FDA 510(k) Premarket Notification

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

CLEARED

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