FDA 510(k) Premarket Notification

K033178 ULTRABIO

CLEARED

Aug 4, 2004
308 days to decision

K033178 · Product code: **MUI** · Radiology
Source: https://www.510kdatabase.net/k033178/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Coupling, Ultrasound (MUI)
Date received	Oct 1, 2003
Decision date	Aug 4, 2004
Days to decision	308 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