FDA 510(k) Premarket Notification

K021132 UNI-PATCH ULTRASOUND COUPLING GEL

CLEARED

May 15, 2002
36 days to decision

K021132 · Product code: **MUI** · Radiology
Source: https://www.510kdatabase.net/k021132/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Coupling, Ultrasound (MUI)
Date received	Apr 9, 2002
Decision date	May 15, 2002
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**The Ludlow Company LP**
Location	Chicopee, MA, US
Contact	M. BETH RICE
510(k) history	3 submissions · 3 cleared · 2001-2002