

K973362 NEEDLE GUIDE/GRIDOct 1, 1997
23 days to decisionK973362 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k973362/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Sep 8, 1997
Decision date	Oct 1, 1997
Days to decision	23 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Protek Medical Products, Inc.
Location	Iowa City, IA, US
Contact	RICK L PRUTER
510(k) history	9 submissions · 9 cleared · 1997-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k973362/> 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 20, 2026