FDA 510(k) Premarket Notification

K973362 NEEDLE GUIDE/GRID

CLEARED

Oct 1, 1997
23 days to decision

K973362 · 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