FDA 510(k) Premarket Notification

K971790 KNOLL/MIDUS (MALE IMPOTENCE DIAGNOSTIC ULTRASONIC SYSTEM)

CLEARED

Dec 17, 1997
217 days to decision

K971790 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k971790/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 14, 1997
Decision date	Dec 17, 1997
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Urometrics, Inc.**
Location	St. Paul, MN, US
Contact	PHILLIP A MESSINA
510(k) history	3 submissions · 2 cleared · 1997-2000