

**K971790 KNOLL/MIDUS (MALE IMPOTENCE DIAGNOSTIC
ULTRASONIC SYSTEM)**Dec 17, 1997
217 days to decisionK971790 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971790/> 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 14, 2026