FDA 510(k) Premarket Notification

K911043 HEMISPHERE MULTIPLANE ENDORECTAL PROBE

CLEARED

Oct 9, 1991
215 days to decision

K911043 · Product code: **ITX** · Radiology
Source: https://www.510kdatabase.net/k911043/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Mar 8, 1991
Decision date	Oct 9, 1991
Days to decision	215 days
Third-party review	No

APPLICANT

Company	**Pie Medical Equipment B.V.**
Location	Maastricht, NL
Contact	RIKERS
510(k) history	8 submissions · 8 cleared · 1990-1998