FDA 510(k) Premarket Notification

K875128 TRANS/R NEEDLE GUIDE

CLEARED

Apr 15, 1988
122 days to decision

K875128 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k875128/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Dec 15, 1987
Decision date	Apr 15, 1988
Days to decision	122 days
Third-party review	No

APPLICANT

Company	**CIVCO Medical Instruments Co., Inc.**
Location	Walker, MI, US
Contact	VICTOR J WEDEL
510(k) history	29 submissions · 29 cleared · 1982-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k875128/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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