FDA 510(k) Premarket Notification

CLEARED

Jun 20, 1997
129 days to decision

K970514 DISPOSABLE TRANSRECTAL/TRANSVAGINAL/ENDOCAVITY ULTRASOUND NEEDLE INSTRUMENT GUIDE

K970514 · Product code: **ITX** · Radiology
Source: https://www.510kdatabase.net/k970514/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Feb 11, 1997
Decision date	Jun 20, 1997
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k970514/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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