

K131528 NON-PYROGENIC ULTRASOUND TRANSDUCER COVERJun 11, 2013
14 days to decisionK131528 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k131528/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	May 28, 2013
Decision date	Jun 11, 2013
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131528/> 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 17, 2026