

**K013721 SYNTHETIC POLYSIOPRENE ULTRASOUND  
TRANSDUCER COVER**Dec 28, 2001  
49 days to decisionK013721 · Product code: ITX · Radiology  
Source: <https://www.510kdatabase.net/k013721/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Nov 9, 2001
Decision date	Dec 28, 2001
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>CIVCO Medical Instruments Co., Inc.</b>
Location	Walker, MI, US
Contact	THERESA LEINEN
510(k) history	29 submissions · 29 cleared · 1982-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013721/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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