

**K163313 ASTRA TEE Transesophageal Probe Reprocessor,  
ASTRA VR Endovaginal/Endorectal Probe Reprocessor**Jun 9, 2017  
198 days to decisionK163313 · Product code: ITX · Radiology  
Source: <https://www.510kdatabase.net/k163313/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Nov 23, 2016
Decision date	Jun 9, 2017
Days to decision	198 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	Kevin Mader
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/k163313/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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