

K233109 TP Pivot Pro™ Needle GuideDec 22, 2023
86 days to decisionK233109 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k233109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Sep 27, 2023
Decision date	Dec 22, 2023
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Civco Medical Solutions
Location	Kalona, IA, US
Contact	James Leong
510(k) history	2 submissions · 2 cleared · 2019-2023

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