

**K092619 ETRAX NEEDLE SYSTEM, ETRAX VARIABLE ANGLE
NEEDLE GUIDANCE SYSTEM, VIRTUTRAX UNIVERSAL
TRACKER**Nov 13, 2009
79 days to decisionK092619 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k092619/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Aug 26, 2009
Decision date	Nov 13, 2009
Days to decision	79 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Civco
Location	Orange City, IA, US
Contact	JAMES LEONG
510(k) history	2 submissions · 2 cleared · 2007-2009

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