FDA 510(k) Premarket Notification

K160806 Verza Guidance System

CLEARED

Aug 5, 2016
134 days to decision

K160806 · Product code: **ITX** · Radiology
Source: https://www.510kdatabase.net/k160806/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Mar 24, 2016
Decision date	Aug 5, 2016
Days to decision	134 days
Third-party review	No
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