FDA 510(k) Premarket Notification

CLEARED

K163313 ASTRA TEE Transesophageal Probe Reprocessor, ASTRA VR Endovaginal/Endorectal Probe Reprocessor

Jun 9, 2017
198 days to decision

K163313 · Product code: **ITX** · Radiology
Source: https://www.510kdatabase.net/k163313/

SUBMISSION DETAILS

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

Company	**CIVCO Medical Instruments Co., Inc.**
Location	Walker, MI, US
Contact	Kevin Mader
510(k) history	29 submissions · 29 cleared · 1982-2023