

K232986 VariTrax Sternal CircumFixation SystemJan 30, 2024
130 days to decisionK232986 · Product code: **JDQ** · Orthopedic
Source: <https://www.510kdatabase.net/k232986/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cerclage, Fixation (JDQ)
Date received	Sep 22, 2023
Decision date	Jan 30, 2024
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Circumfix Solutions, Inc.
Location	Collierville, TN, US
Contact	Ken Richardson
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	MRC Global
Contact	Danielle Besal

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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