

K192465 DigiFix Sterile KitOct 10, 2019
31 days to decisionK192465 · Product code: **JEC** · Orthopedic
Source: <https://www.510kdatabase.net/k192465/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Component, Traction, Invasive (JEC)
Date received	Sep 9, 2019
Decision date	Oct 10, 2019
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Virak Orthopedics, LLC
Location	Harrison, NJ, US
Contact	Virak Tan
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Mrc-X, LLC
Contact	Christine Scifert

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

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