FDA 510(k) Premarket Notification

K190166 TriMed Nitinol Staple System

CLEARED

Jul 1, 2019
151 days to decision

K190166 · Product code: **JDR** · Orthopedic
Source: https://www.510kdatabase.net/k190166/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Fixation, Bone (JDR)
Date received	Jan 31, 2019
Decision date	Jul 1, 2019
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**TriMed, Inc.**
Location	Saugus, CA, US
Contact	David Medoff
510(k) history	36 submissions · 36 cleared · 2005-2026

REGULATORY CONSULTANT

Consulting firm	**Jean Asquith**
Contact	Jean Asquith

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