FDA 510(k) Premarket Notification

K190722 TriMAX Implant System

CLEARED

Aug 16, 2019
149 days to decision

K190722 · Product code: **JDR** · Orthopedic
Source: https://www.510kdatabase.net/k190722/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Fixation, Bone (JDR)
Date received	Mar 20, 2019
Decision date	Aug 16, 2019
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Crossroads Extemity Systems, LLC**
Location	Memphis, TN, US
Contact	Chad Hollis
510(k) history	3 submissions · 3 cleared · 2019-2020

REGULATORY CONSULTANT

Consulting firm	**Mrc X, LLC**
Contact	Theresa Leister

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