FDA 510(k) Premarket Notification

K173910 Impress SFS System

CLEARED

Sep 14, 2018
266 days to decision

K173910 · Product code: **JDQ** · Orthopedic
Source: https://www.510kdatabase.net/k173910/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cerclage, Fixation (JDQ)
Date received	Dec 22, 2017
Decision date	Sep 14, 2018
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cable Fix Medical, LLC**
Location	Hernando, MS, US
Contact	Carey Bryant
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	**Msquared Associates, Inc.**
Contact	Janet Akil

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