FDA 510(k) Premarket Notification

CLEARED

K163471 Kalitec Direct InSePtion™ MIS Fixation System

Mar 16, 2017
94 days to decision

K163471 · Product code: **PEK** · Orthopedic
Source: https://www.510kdatabase.net/k163471/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Dec 12, 2016
Decision date	Mar 16, 2017
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kalitec Direct, LLC**
Location	Round Rock, TX, US
Contact	KEITH CANNAN
510(k) history	9 submissions · 9 cleared · 2011-2018