FDA 510(k) Premarket Notification

K201704 CoFix System

CLEARED

Aug 4, 2020
43 days to decision

K201704 · Product code: **PEK** · Orthopedic
Source: https://www.510kdatabase.net/k201704/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Spinous Process Plate (PEK)
Date received	Jun 22, 2020
Decision date	Aug 4, 2020
Days to decision	43 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Paradigm Spine GmbH**
Location	New York, NY, US
Contact	Branko Sostarko
510(k) history	2 submissions · 2 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Justin Eggleton

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