

K201704 CoFix SystemAug 4, 2020
43 days to decisionK201704 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201704/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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