

K153302 coflex-IFSep 8, 2016
300 days to decisionK153302 · Product code: **PEK** · Orthopedic
Source: <https://www.510kdatabase.net/k153302/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Nov 13, 2015
Decision date	Sep 8, 2016
Days to decision	300 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Paradigm Spine, LLC
Location	Washington, DC, US
Contact	Marc Viscogliosi
510(k) history	11 submissions · 4 cleared · 2008-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153302/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026