

## K212781 Posterior Fusion Plate/HA Posterior Fusion Plate, Minuteman G3 MIS Fusion Plate, HA Minuteman G3 MIS Fusion Plate, HA Minuteman G3-R MIS Fusion Plate

Dec 15, 2021  
105 days to decision

K212781 · Product code: PEK · Orthopedic  
Source: <https://www.510kdatabase.net/k212781/>

### SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Sep 1, 2021
Decision date	Dec 15, 2021
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

### APPLICANT

Company	<b>Spinal Simplicity, LLC</b>
Location	Philedelphia, PA, US
Contact	Adam Rogers
510(k) history	14 submissions · 14 cleared · 2015-2025

### CLINICAL EVIDENCE - NCT01455805

#### Minuteman Spinal Fusion Implant Versus Surgical Decompression for Lumbar Spinal Stenosis

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	48 patients (actual)
Study sites	4 sites
Condition studied	Lumbar Spinal Stenosis; Spondylolisthesis; Degenerative Disc Disease
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Mar 1, 2024
Sponsor	Spinal Simplicity LLC (Industry)

#### Primary outcome

Change from baseline of clinical efficacy up to 60 months post procedure

#### Secondary outcome

measures of quality of life

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT01455805](https://clinicaltrials.gov/study/NCT01455805)