

K143631 Benefix Interspinous Fixation SystemSep 3, 2015
255 days to decisionK143631 · Product code: **PEK** · Orthopedic
Source: <https://www.510kdatabase.net/k143631/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Dec 22, 2014
Decision date	Sep 3, 2015
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	U&I Corporation
Location	Uijeongbu-Si, Gyeonggi-Do, KR
Contact	Young-Geun Kim
510(k) history	23 submissions · 23 cleared · 2013-2022

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