

K162849 Huvex Interspinous Fixation SystemFeb 16, 2017
128 days to decisionK162849 · Product code: **PEK** · Orthopedic
Source: <https://www.510kdatabase.net/k162849/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Oct 11, 2016
Decision date	Feb 16, 2017
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dio Medical Co., Ltd.
Location	Santa Fe Springs, CA, US
Contact	LEE SUNG-HEE
510(k) history	7 submissions · 7 cleared · 2010-2017

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