

K223790 Huvex Interspinous Fusion SystemMar 9, 2023
80 days to decisionK223790 · Product code: **PEK** · Orthopedic
Source: <https://www.510kdatabase.net/k223790/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Dec 19, 2022
Decision date	Mar 9, 2023
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dio Medical Corp.
Location	East Norriton, PA, US
Contact	Milan George
510(k) history	1 submissions · 1 cleared · 2023-2023

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