

**K222572 FORTIS and HANA Anterior Cervical Plate System,
Rex Anterior Cervical Plate System, and BALTEUM™ &
BALTEUM-ONE™ Lumbar Plate System**Oct 18, 2022
54 days to decisionK222572 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k222572/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Aug 25, 2022
Decision date	Oct 18, 2022
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dio Medical Corporation
Location	East Norriton, PA, US
Contact	Milan George
510(k) history	4 submissions · 4 cleared · 2022-2022

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