

K213820 BALTEUM - ONE™ Lumbar Plate SystemMar 25, 2022
107 days to decisionK213820 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k213820/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Dec 8, 2021
Decision date	Mar 25, 2022
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Huvexel Co. , Ltd.
Location	Seongnam-Si, KR
Contact	Sung Kyu Hur
510(k) history	8 submissions · 8 cleared · 2017-2022

REGULATORY CONSULTANT

Consulting firm	Dio Medical Corporation
Contact	Milan George

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213820/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026