

K200846 Balteum™ Lumbar Plate SystemMay 5, 2020
35 days to decisionK200846 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k200846/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Mar 31, 2020
Decision date	May 5, 2020
Days to decision	35 days
Third-party review	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

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