

K210035 ZESPIN SI Joint Fusion System, MegaCerfix Posterior Cervical Fixation System, MegaCerfix Anterior Cervical Plate System, Spinema Lumbar Plate System

Feb 16, 2021
41 days to decision

K210035 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k210035/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Jan 6, 2021
Decision date	Feb 16, 2021
Days to decision	41 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aegis Spine
Location	Englewood, CO, US
Contact	Kay Kwon
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Empirical Testing Corp
Contact	Meredith Lee May

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k210035/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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