

K200224 SEA-LINK Anterior Cervical Plate SystemMar 24, 2020
55 days to decisionK200224 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k200224/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Jan 29, 2020
Decision date	Mar 24, 2020
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Indius Medical Technologies Pvt. , Ltd.
Location	Pune, IN
Contact	Aditya Ingalthalikar
510(k) history	2 submissions · 2 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Empirical Testing Corp
Contact	Nathan Wright

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

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