

K200937 ACURA Stabilization SystemOct 26, 2020
201 days to decisionK200937 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k200937/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Apr 8, 2020
Decision date	Oct 26, 2020
Days to decision	201 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200937/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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