

K183168 OpenLoc-L Spinal Fixation SystemDec 11, 2018
25 days to decisionK183168 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k183168/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Nov 16, 2018
Decision date	Dec 11, 2018
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	L & K Biomed Co., Ltd.
Location	Yongin-Si, KR
Contact	Jihyeon Seo
Website	https://www.lkbiomed.com
510(k) history	54 submissions · 54 cleared · 2010-2026

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