

K162801 CastleLoc Spinal Fixation SystemNov 3, 2016
29 days to decisionK162801 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k162801/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Oct 5, 2016
Decision date	Nov 3, 2016
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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