

K153656 PathLoc-SI Joint Fusion SystemNov 14, 2016
329 days to decisionK153656 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k153656/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Dec 21, 2015
Decision date	Nov 14, 2016
Days to decision	329 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153656/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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