FDA 510(k) Premarket Notification

K153439 PathLoc-C Posterior Cervical Fixation System

CLEARED

Jul 21, 2016
237 days to decision

K153439 · Product code: **NKG** · Orthopedic
Source: https://www.510kdatabase.net/k153439/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	Nov 27, 2015
Decision date	Jul 21, 2016
Days to decision	237 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