

K100805 GALLERY LAMINOPLASTY FIXATION SYSTEMJul 20, 2010
120 days to decisionK100805 · Product code: **NQW** · Orthopedic
Source: <https://www.510kdatabase.net/k100805/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spine, Plate, Laminoplasty, Metal (NQW)
Date received	Mar 22, 2010
Decision date	Jul 20, 2010
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomet Spine (Aka Ebi, LLC)
Location	Parsippany, NJ, US
Contact	SHIKHA GOLA
510(k) history	13 submissions · 13 cleared · 2010-2014

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