FDA 510(k) Premarket Notification

K103284 LAMINOPLASY PLATING SYSTEM

CLEARED

Dec 2, 2010
27 days to decision

K103284 · Product code: **NQW** · Orthopedic
Source: https://www.510kdatabase.net/k103284/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spine, Plate, Laminoplasty, Metal (NQW)
Date received	Nov 5, 2010
Decision date	Dec 2, 2010
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Aesculap Implant Systems, Inc.**
Location	Center Valley, PA, US
Contact	LISA M BOYLE
510(k) history	22 submissions · 22 cleared · 2007-2016