FDA 510(k) Premarket Notification

K150468 Laminectomy Rongeurs, Kerrison Rongeurs, IVD Rongeurs

CLEARED

Feb 29, 2016
371 days to decision

K150468 · Product code: **HAE** · Neurology
Source: https://www.510kdatabase.net/k150468/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rongeur, Manual (HAE)
Date received	Feb 23, 2015
Decision date	Feb 29, 2016
Days to decision	371 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**K2 Medical GmbH & Co. KG**
Location	Tuttlingen, DE
Contact	Harald Jung
510(k) history	2 submissions · 2 cleared · 2012-2016