FDA 510(k) Premarket Notification

K180949 Steribite

CLEARED

Nov 8, 2018
211 days to decision

K180949 · Product code: **HAE** · Neurology
Source: https://www.510kdatabase.net/k180949/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rongeur, Manual (HAE)
Date received	Apr 11, 2018
Decision date	Nov 8, 2018
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Rjr Surgical, Inc.**
Location	Cleveland, OH, US
Contact	John Redmond
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	**Backroads Consulting, Inc.**
Contact	Karen E. Warden

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov