FDA 510(k) Premarket Notification

K221818 Rebellion

CLEARED

Oct 7, 2022
106 days to decision

K221818 · Product code: **HAE** · Neurology
Source: https://www.510kdatabase.net/k221818/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Rongeur, Manual (HAE)
Date received	Jun 23, 2022
Decision date	Oct 7, 2022
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Phantom Multi-Bite Kerrison Rongeur

APPLICANT

Company	**Morpheus AG**
Location	Spaichingen, DE
Contact	Timo Rack
510(k) history	3 submissions · 3 cleared · 2021-2023