FDA 510(k) Premarket Notification

K193383 SnugKap

CLEARED

Jun 7, 2021
550 days to decision

K193383 · Product code: **MVA** · Neurology
Source: https://www.510kdatabase.net/k193383/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial (MVA)
Date received	Dec 5, 2019
Decision date	Jun 7, 2021
Days to decision	550 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Headstart, Ltd.**
Location	Elk Grove Village, IL, US
Contact	James McCartney
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Dave McGurl

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