FDA 510(k) Premarket Notification

K210109 visor2 system

CLEARED

Apr 8, 2022
444 days to decision

K210109 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k210109/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jan 19, 2021
Decision date	Apr 8, 2022
Days to decision	444 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Eemagine Medical Imaging Solutions GmbH**
Location	Mukwonago, WI, US
Contact	Maarten Van De Velde
510(k) history	8 submissions · 8 cleared · 2000-2024

REGULATORY CONSULTANT

Consulting firm	**Quality & Regulatory Associates, LLC**
Contact	Gary J Syring

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