FDA 510(k) Premarket Notification

K202391 DIR 800

CLEARED

Jan 21, 2021
153 days to decision

K202391 · Product code: **IZI** · Neurology
Source: https://www.510kdatabase.net/k202391/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Aug 21, 2020
Decision date	Jan 21, 2021
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aesculap, Inc.**
Location	Burlingame, CA, US
Contact	Kathy A. Racosky
510(k) history	207 submissions · 201 cleared · 1991-2025