

K202391 DIR 800Jan 21, 2021
153 days to decisionK202391 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202391/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026