FDA 510(k) Premarket Notification

K213813 DuraFuse Clip and Applier System

CLEARED

Jul 22, 2022
227 days to decision

K213813 · Product code: **FZP** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k213813/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clip, Implantable (FZP)
Date received	Dec 7, 2021
Decision date	Jul 22, 2022
Days to decision	227 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neuramedica, Inc.**
Location	Oregon City, OR, US
Contact	Rachel Dreilinger
510(k) history	1 submissions · 1 cleared · 2022-2022