FDA 510(k) Premarket Notification

K221481 NeutrArt

CLEARED

Sep 23, 2022
123 days to decision

K221481 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k221481/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	May 23, 2022
Decision date	Sep 23, 2022
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Asset Medikal Tasarim As.**
Location	Istanbul, TR
Contact	Ebru Sirali
510(k) history	4 submissions · 4 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	**Licensale, Inc.**
Contact	Raymond Kelly

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