FDA 510(k) Premarket Notification

# K201872 NeutrArt

**CLEARED**

Jan 5, 2021
182 days to decision

K201872 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k201872/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received | Jul 7, 2020 |
| Decision date | Jan 5, 2021 |
| Days to decision | 182 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

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|---|---|
| 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