FDA 510(k) Premarket Notification

**CLEARED**

# K201257 MI.BO. ® MyoBoost EMS System (MB-1000, MB-600, MB-400)

Apr 6, 2021
330 days to decision

K201257 · Product code: **NGX** · Physical Medicine
Source: https://www.510kdatabase.net/k201257/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stimulator, Muscle, Powered, For Muscle Conditioning (NGX) |
| Date received | May 11, 2020 |
| Decision date | Apr 6, 2021 |
| Days to decision | 330 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Arrive Systems, Inc.** |
| Location | New Ark, DE, US |
| Contact | Aseem Gupta |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Iuvo Consulting, LLC** |
| Contact | Rhonda Alexander |

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