FDA 510(k) Premarket Notification

# K203498 LX9max

**CLEARED**

Jul 2, 2021
217 days to decision

K203498 · Product code: **IRP** · Physical Medicine
Source: https://www.510kdatabase.net/k203498/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Massager, Powered Inflatable Tube (IRP) |
| Date received | Nov 27, 2020 |
| Decision date | Jul 2, 2021 |
| Days to decision | 217 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Daesung Maref Co., Ltd.** |
| Location | Buena Park, CA, US |
| Contact | Su Hyeon So |
| 510(k) history | 14 submissions · 14 cleared · 2011-2023 |