FDA 510(k) Premarket Notification

# K192337 Zeroveno

**CLEARED**

Jun 22, 2020
299 days to decision

K192337 · Product code: **JOW** · Cardiovascular
Source: https://www.510kdatabase.net/k192337/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Sleeve, Limb, Compressible (JOW) |
| Date received | Aug 28, 2019 |
| Decision date | Jun 22, 2020 |
| Days to decision | 299 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Dimedi Co., Ltd.** |
| Location | Wonju-Si, KR |
| Contact | Nam Youn |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Wise Company, Inc.** |
| Contact | Sanglok Lee |

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