**CLEARED**

Aug 22, 2024
590 days to decision

# K230071 Femur Reconstruction Interlocking Nail System, Femur Retrograde Interlocking Nail System, Humerus Interlocking Nail System, Tibia Interlocking Nail System, Compression Hip Nail System

K230071 · Product code: **HSB** · Orthopedic
Source: https://www.510kdatabase.net/k230071/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Rod, Fixation, Intramedullary And Accessories (HSB) |
| Date received | Jan 10, 2023 |
| Decision date | Aug 22, 2024 |
| Days to decision | 590 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Tdm Co., Ltd.** |
| Location | Gwangju, KR |
| Contact | Jung Wook Choi |
| 510(k) history | 11 submissions · 11 cleared · 2018-2024 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Mtechgroup** |
| Contact | Dave Kim |

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