FDA 510(k) Premarket Notification

# K232049 IS-III active Short Implant

**CLEARED**

Mar 28, 2024
262 days to decision

K232049 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k232049/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received | Jul 10, 2023 |
| Decision date | Mar 28, 2024 |
| Days to decision | 262 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Neobiotech Co., Ltd.** |
| Location | Santa Fe Springs, CA, US |
| Contact | Young-Ku Heo |
| 510(k) history | 17 submissions · 17 cleared · 2004-2024 |

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **Withus Group, Inc.** |
| Contact | April Lee |

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