

K231753 Oneday Implant AbutmentFeb 21, 2024
251 days to decisionK231753 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k231753/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jun 15, 2023
Decision date	Feb 21, 2024
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Oneday Biotech Co., Ltd.
Location	Daegu, KR
Contact	Jinhwan Kim
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

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](https://accessdata.fda.gov)

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