FDA 510(k) Premarket Notification

K232528 Protective Cap

CLEARED

Apr 30, 2024
253 days to decision

K232528 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k232528/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Aug 21, 2023
Decision date	Apr 30, 2024
Days to decision	253 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	Yoeng Ku Hoe
510(k) history	17 submissions · 17 cleared · 2004-2024

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k232528/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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