FDA 510(k) Premarket Notification

K220253 Eco Abutment, Multiunit Abutment

CLEARED

Aug 18, 2023
564 days to decision

K220253 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k220253/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jan 31, 2022
Decision date	Aug 18, 2023
Days to decision	564 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dio Corporation**
Location	Los Angeles, CA, US
Contact	Cho Hye-won
510(k) history	14 submissions · 14 cleared · 2010-2023

REGULATORY CONSULTANT

Consulting firm	**Dio USA**
Contact	Peter Kang

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