FDA 510(k) Premarket Notification

K231915 Zfx Abutments

CLEARED

Mar 1, 2024
246 days to decision

K231915 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k231915/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jun 29, 2023
Decision date	Mar 1, 2024
Days to decision	246 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zfx GmbH - A Company of Zimvie**
Location	Dachau, DE
Contact	Ana Leitão
510(k) history	1 submissions · 1 cleared · 2024-2024