FDA 510(k) Premarket Notification

K231566 ICX-Implant System

CLEARED

Sep 5, 2024
463 days to decision

K231566 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k231566/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	May 31, 2023
Decision date	Sep 5, 2024
Days to decision	463 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medentis Medical GmbH**
Location	Bad Neuenahr-Ahrweiler, DE
Contact	Alexander Scholz
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**PaxMed International, LLC**
Contact	Floyd G. Larson

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