FDA 510(k) Premarket Notification

K233805 K5

CLEARED

Sep 3, 2024
279 days to decision

K233805 · Product code: **EIA** · Dental
Source: https://www.510kdatabase.net/k233805/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Nov 29, 2023
Decision date	Sep 3, 2024
Days to decision	279 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Osstem Implant Co., Ltd. Chair Business**
Location	Ansan-Si, KR
Contact	Sangyong Lee
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Hiossen, Inc.**
Contact	Peter Lee

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