FDA 510(k) Premarket Notification

K221684 Osstem Abutment System

CLEARED

Sep 8, 2022
90 days to decision

K221684 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k221684/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jun 10, 2022
Decision date	Sep 8, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Osstem Implant Co., Ltd.**
Location	Busan, KR
Contact	Seungju Kang
Website	https://www.osstem.com
510(k) history	68 submissions · 68 cleared · 2006-2026

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