FDA 510(k) Premarket Notification

K182091 Osstem Abutment System

CLEARED

Jul 12, 2019
343 days to decision

K182091 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k182091/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Aug 3, 2018
Decision date	Jul 12, 2019
Days to decision	343 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Osstem Implant Co., Ltd.**
Location	Busan, KR
Contact	Jungmin Yoo
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