FDA 510(k) Premarket Notification

K183347 K3

CLEARED

Sep 4, 2019
275 days to decision

K183347 · Product code: **EIA** · Dental
Source: https://www.510kdatabase.net/k183347/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Dec 3, 2018
Decision date	Sep 4, 2019
Days to decision	275 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Osstem Implant Co., Ltd.**
Location	Busan, KR
Contact	Hyeri Han
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