FDA 510(k) Premarket Notification

K161604 OSSTEM Implant System

CLEARED

Oct 17, 2016
129 days to decision

K161604 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k161604/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jun 10, 2016
Decision date	Oct 17, 2016
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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