FDA 510(k) Premarket Notification

K080387 HU II / HS II FIXTURE SYSTEM

CLEARED

Mar 7, 2008
23 days to decision

K080387 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k080387/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Feb 13, 2008
Decision date	Mar 7, 2008
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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