

K080387 HU II / HS II FIXTURE SYSTEMMar 7, 2008
23 days to decisionK080387 · Product code: **DZE** · DentalSource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080387/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 25, 2026