

K160106 LUNA DENTAL IMPLANT SYSTEMAug 26, 2016
220 days to decisionK160106 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k160106/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jan 19, 2016
Decision date	Aug 26, 2016
Days to decision	220 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Shinhung Mst Co., Ltd.
Location	Wonju-Si, KR
Contact	Sunbyung Lee
510(k) history	7 submissions · 7 cleared · 2013-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160106/> 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 May 27, 2026