

K222707 IH Implant SystemJul 7, 2023
303 days to decisionK222707 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k222707/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 7, 2022
Decision date	Jul 7, 2023
Days to decision	303 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sewonmedix, Inc.
Location	Busan, KR
Contact	Jinsoo Lee
510(k) history	2 submissions · 2 cleared · 2016-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222707/> 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