

**K222211 Implant Direct Dental Implant Systems Portfolio - MR
Conditional**Feb 2, 2023
192 days to decisionK222211 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k222211/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jul 25, 2022
Decision date	Feb 2, 2023
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Implant Direct Sybron Manufacturing, LLC
Location	Calabasas, CA, US
Contact	Reina Choi
510(k) history	17 submissions · 17 cleared · 2013-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222211/>. 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 13, 2026