

K220978 TSX ImplantsSep 14, 2022
163 days to decisionK220978 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k220978/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Apr 4, 2022
Decision date	Sep 14, 2022
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biomet 3i, LLC
Location	Palm Beach Gardens, FL, US
Contact	Mariela Cabarcas
510(k) history	7 submissions · 7 cleared · 2019-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220978/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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