FDA 510(k) Premarket Notification

K220978 TSX Implants

CLEARED

Sep 14, 2022
163 days to decision

K220978 · Product code: **DZE** · Dental
Source: 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