FDA 510(k) Premarket Notification

K210220 Kontact Dental Implant System

CLEARED

Jun 18, 2021
142 days to decision

K210220 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k210220/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jan 27, 2021
Decision date	Jun 18, 2021
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biotech Dental, Sas**
Location	Salon De Provence, FR
Contact	Delphine Mercier
510(k) history	3 submissions · 3 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	**PaxMed International, LLC**
Contact	Kevin A. Thomas

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov