FDA 510(k) Premarket Notification

K202909 CreoDent Solidex Customized Abutment

CLEARED

Apr 2, 2021
185 days to decision

K202909 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k202909/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Sep 29, 2020
Decision date	Apr 2, 2021
Days to decision	185 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Creodent Prosthetics, Ltd.**
Location	New York, NY, US
Contact	Calvin Shim
510(k) history	9 submissions · 9 cleared · 2013-2022

REGULATORY CONSULTANT

Consulting firm	**Aclivi, LLC**
Contact	Chris Brown

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