FDA 510(k) Premarket Notification

K223638 Neodent Implant System - Helix Short Implant System

CLEARED

Jun 23, 2023
200 days to decision

K223638 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k223638/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Dec 5, 2022
Decision date	Jun 23, 2023
Days to decision	200 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Jjgc Industria E Comercio DE Materiais Dentarios S.A.**
Location	Curitiba, BR
Contact	Barbara Uzae
510(k) history	28 submissions · 28 cleared · 2016-2023

REGULATORY CONSULTANT

Consulting firm	**Straumann USA, LLC**
Contact	Jennifer M Jackson

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