FDA 510(k) Premarket Notification

K242686 Neodent Implant System

CLEARED

Dec 4, 2024
89 days to decision

K242686 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k242686/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Sep 6, 2024
Decision date	Dec 4, 2024
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Jjgc Ind?stria E Com?rcia DE Materiais Dent?rios S.A.**
Location	Curitiba, BR
Contact	Leticia Milani
510(k) history	2 submissions · 2 cleared · 2024-2025

REGULATORY CONSULTANT

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

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