FDA 510(k) Premarket Notification

K211921 S.I.N. Dental Implant System

CLEARED

Oct 20, 2021
121 days to decision

K211921 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k211921/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jun 21, 2021
Decision date	Oct 20, 2021
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**S.I.N. ? Sistema DE Implante Nacional S.A.**
Location	Sao Paulo, BR
Contact	Denise Domiciano
510(k) history	17 submissions · 17 cleared · 2017-2024

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