FDA 510(k) Premarket Notification

K221851 Lumina-PTFE Titanium

CLEARED

Dec 8, 2023
529 days to decision

K221851 · Product code: **NPK** · Dental
Source: https://www.510kdatabase.net/k221851/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Synthetic, Intraoral (NPK)
Date received	Jun 27, 2022
Decision date	Dec 8, 2023
Days to decision	529 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Criteria Industria E Comercio DE Produtos Medicinais**
Location	Sao Carlos, BR
Contact	Andre Hamar Braga
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Pr Servicos Regulatorios Administrativos Ltda**
Contact	Graziela Brum

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