FDA 510(k) Premarket Notification

K202617 Metapex Plus

CLEARED

Apr 14, 2021
217 days to decision

K202617 · Product code: **KIF** · Dental
Source: https://www.510kdatabase.net/k202617/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	Sep 9, 2020
Decision date	Apr 14, 2021
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Meta Biomed Co., Ltd.**
Location	Elmhurst, NY, US
Contact	Suk Song Oh
510(k) history	21 submissions · 21 cleared · 2003-2024

REGULATORY CONSULTANT

Consulting firm	**Withus Group, Inc.**
Contact	April Lee

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