

K230010 ADSEAL PlusApr 13, 2023
100 days to decisionK230010 · Product code: **KIF** · Dental
Source: <https://www.510kdatabase.net/k230010/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	Jan 3, 2023
Decision date	Apr 13, 2023
Days to decision	100 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.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230010/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026