

K242435 Dental Barrier and SleevesOct 18, 2024
63 days to decisionK242435 · Product code: **PEM** · Dental
Source: <https://www.510kdatabase.net/k242435/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dental Barriers And Sleeves (PEM)
Date received	Aug 16, 2024
Decision date	Oct 18, 2024
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Wellmed Dental Medical Supply Co., Ltd.
Location	Shenzhen, CN
Contact	Renxian Tang
510(k) history	3 submissions · 3 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Shanghai SUNGO Management Consulting Co., Ltd.
Contact	Luna Hu

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

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