

K233918 Dental Barrier and SleevesMay 9, 2024
148 days to decisionK233918 · Product code: **PEM** · Dental
Source: <https://www.510kdatabase.net/k233918/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dental Barriers And Sleeves (PEM)
Date received	Dec 13, 2023
Decision date	May 9, 2024
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Yongqing Huaguan Dental Instruments Factory
Location	Langfang, CN
Contact	ZengYan Wu
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Shanghai SUNGO Management Consulting Co., Ltd.
Contact	Jarvis Wu

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

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