

K220662 Disposable Barrier SleevesMay 11, 2022
65 days to decisionK220662 · Product code: **PEM** · Dental
Source: <https://www.510kdatabase.net/k220662/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dental Barriers And Sleeves (PEM)
Date received	Mar 7, 2022
Decision date	May 11, 2022
Days to decision	65 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Premium Plus (Dongguan) Limited
Location	Dongguan, CN
Contact	Jessica Mao
510(k) history	3 submissions · 3 cleared · 2022-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220662/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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