

K163447 Premium Plus Disposable Barrier SleeveJun 20, 2017
194 days to decisionK163447 · Product code: **PEM** · Dental
Source: <https://www.510kdatabase.net/k163447/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dental Barriers And Sleeves (PEM)
Date received	Dec 8, 2016
Decision date	Jun 20, 2017
Days to decision	194 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Premium Plus International Limited
Location	Hong Kong, CN
Contact	JESSICA MAO
510(k) history	4 submissions · 4 cleared · 2010-2017

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