

K151123 Pac-Dent Barrier Sleeve, Cover-It(TM) Barrier FilmMar 3, 2016
310 days to decisionK151123 · Product code: **PEM** · Dental
Source: <https://www.510kdatabase.net/k151123/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dental Barriers And Sleeves (PEM)
Date received	Apr 28, 2015
Decision date	Mar 3, 2016
Days to decision	310 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pac-Dent International, Inc.
Location	Walnut, CA, US
Contact	Wenying Zhu
510(k) history	9 submissions · 9 cleared · 2013-2017

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