

K201604 Plasdent Disposable Barrier Sleeves and Barrier FilmDec 23, 2020
191 days to decisionK201604 · Product code: **PEM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201604/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dental Barriers And Sleeves (PEM)
Date received	Jun 15, 2020
Decision date	Dec 23, 2020
Days to decision	191 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Plasdent Corporation
Location	Pomona, CA, US
Contact	Belen G Walayat
510(k) history	1 submissions · 1 cleared · 2020-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201604/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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