

K183263 UNiPACK Barrier Sleeve and Barrier Film and UNiGLIDE Barrier EnvelopeJun 14, 2019
203 days to decisionK183263 · Product code: **PEM** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k183263/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dental Barriers And Sleeves (PEM)
Date received	Nov 23, 2018
Decision date	Jun 14, 2019
Days to decision	203 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Unipack Medical Corporation
Location	Santa Fe Springs, CA, US
Contact	Joe Pomparelli
510(k) history	1 submissions · 1 cleared · 2019-2019

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