

K190949 ScanX Barrier EnvelopesJul 26, 2019
106 days to decisionK190949 · Product code: **PEM** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k190949/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dental Barriers And Sleeves (PEM)
Date received	Apr 11, 2019
Decision date	Jul 26, 2019
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Air Techniques, Inc.
Location	Hicksville, NY, US
Contact	Samir Ghevariya
510(k) history	18 submissions · 18 cleared · 1995-2019

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