

**K190484 BH Medical Dental Barrier Sleeves and Barrier Film**Sep 10, 2019  
195 days to decisionK190484 · Product code: **PEM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k190484/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dental Barriers And Sleeves (PEM)
Date received	Feb 27, 2019
Decision date	Sep 10, 2019
Days to decision	195 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Bh Medical Products Co., Ltd.</b>
Location	Dover, DE, US
Contact	Xiaohua TAO
510(k) history	3 submissions · 3 cleared · 2015-2019

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190484/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026