

**K192691 PatCom Single-Use Introducer**Feb 21, 2020  
148 days to decisionK192691 · Product code: **FED** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k192691/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Sep 26, 2019
Decision date	Feb 21, 2020
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>H&amp;A Mui Enterprises, Inc.</b>
Location	Mississauga, CA
Contact	Tammy Mui
510(k) history	2 submissions · 2 cleared · 2020-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192691/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026