

**K181760 Transit-Pellets**Aug 8, 2019  
401 days to decisionK181760 · Product code: **FFX** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k181760/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Jul 3, 2018
Decision date	Aug 8, 2019
Days to decision	401 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Medifactia AB</b>
Location	Gothenburg, SE
Contact	Diana Nystrom
510(k) history	2 submissions · 2 cleared · 2019-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181760/> 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 28, 2026