

K222000 Transit-PelletsJan 18, 2023
195 days to decisionK222000 · Product code: **FFX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k222000/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Jul 7, 2022
Decision date	Jan 18, 2023
Days to decision	195 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Msquared Associates, Inc.
Contact	Cherita James

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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